S. Hrg. 104–520

IMPROPER MEDICARE BILLING BY HOSPITALS NATIONWIDE FOR INVESTIGATIONAL DEVICES AND PROCEDURES

Y 4. G 74/9: S. HRG. 104-520

Improper Medicare Billing by Hospit...

HEARING

BEFORE THE

PERMANENT
SUBCOMMITTEE ON INVESTIGATIONS
OF THE

COMMITTEE ON
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED FOURTH CONGRESS

SECOND SESSION

FEBRUARY 14, 1996

Printed for the use of the Committee on Governmental Affairs

DEPOSITORY

SEP 19 1996

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IMPROPER MEDICARE BILLINGS BY HOSPITALS NATIONWIDE FOR INVESTIGATIONAL DEVICES AND PROCEDURES

WEDNESDAY, FEBRUARY 14, 1996

U.S. SENATE,
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS,
COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10 a.m., in room SD–342, Dirksen Senate Office Building, Hon. William V. Roth, Jr., Chairman of the Subcommittee, presiding.

Present: Senators Roth, Levin, and Dorgan.

Staff present: Harold Damelin, Chief Counsel and Staff Director; Daniel S. Gelber, Minority Chief Counsel; Eric M. Thorson, Chief Investigator; Stephen H. Levin, Senior Counsel; Sallie B. Cribbs, Executive Assistant to the Chief Counsel; Carla J. Martin, Chief Clerk; Ariadne Allan, Investigator; John H. Cobb, Counsel; Michael Bopp, Counsel; Deborah McMahon, Investigator; Suzanne Horner, Librarian; Mary Ailes, Staff Assistant; Katherine O'Connor, Receptionist; Alan Edelman, Counsel to the Minority; Mark Webster, Investigator to the Minority; Gioia Bonmartini (Finance Committee); Libby Wood (Senator Thompson); Helen Albert (Senator Cohen); Sandra Bruce (Senator Levin); Linda Gustitus (Oversight); Doug Fuller, Governmental Affairs Committee; Clayton Heil (Senator Cochran), John Guest (Senator Lieberman), Rick Valentine (Senator Smith); Karen Warner (Senator Specter), Stephanie Mohn (Senator Dorgan); Jeremy Bates (Senator Dorgan); and Kirsten Michael (Senator Gorton).

OPENING STATEMENT OF CHAIRMAN ROTH

Chairman ROTH. The Subcommittee will please come to order. This morning the Subcommittee will present the results of an investigation into the improper or fraudulent billing of certain investigational devices or procedures to the Medicare program. This hearing continues the Subcommittee's longstanding interest in issues involving waste, fraud and abuse in our Nation's health care system.

I would like to thank our senior Democratic Member, Senator Nunn and his staff for their assistance during the course of this investigation, continuing the Subcommittee's tradition of bipartisan cooperation.

Perhaps no other government program is more open to fraud and abuse than Medicare with its huge annual expenditures and inad-

equate protections, Medicare has proven to be an easy and profitable mark for those intent to rip it off.

The General Accounting Office has estimated that the loss to Medicare from fraud and abuse equals approximately $17 billion which is 10 percent of total Medicare spending. And those of us who are working to strengthen Medicare want to ensure that people eligible for Medicare are given the best care possible and that the money will be there to pay for it. That is without question.

My deep concern is that we are not doing enough to stop Medicare fraud where it starts. The answer is not just in more prosecutions or trying to recoup money long after it's been paid; the answer is to administer this program properly and hold accountable those who have the responsibility for the oversight as well as the policies of Medicare.

In other words, put some teeth in the program and make those who would abuse the system think twice before attempting to defraud Medicare. That is the only real way to begin to protect this vital program.

First I want to make clear what this hearing is not about. It is not about Medicare patients receiving a lower quality of care. It is not about denying Medicare patients the latest state-of-the-art treatment. This hearing is about certain institutions who were able to evade the rules resulting in what the IG has estimated to be hundreds of millions of dollars of improper payments.

The focus of this hearing is on investigational medical devices. The term, investigational device, refers to a clinical trial of a medical device in its final stage of testing by the Food and Drug Administration. It is only after such a device is approved by the Food and Drug Administration that it is deemed safe for the general public and available to hospitals nationwide as pacemakers were in recent years.

Until final Food and Drug Administration approval is granted, a device is considered investigational or experimental. And before recently revising its policy, Medicare would not pay for devices and related procedures that had not received final Food and Drug Administration approval.

Throughout a clinical trial, only a very small number of approved physicians can implant or otherwise utilize these devices. In fact, only about 2 percent of all hospitals nationwide are approved by the Food and Drug Administration to perform clinical tests. Typically the cost of developing these devices and the related surgical procedures are borne by the device manufacturer and the participating hospitals. And in only the rarest of cases does the patient pay for an investigational procedure.

The Subcommittee investigation discovered that certain hospitals found a way to have Medicare absorb these costs, Medicare's policy notwithstanding. And they did this primarily by submitting improper bills that did not identify these devices as investigational.

Medicare paid and this drain on Medicare funds through payment for disallowed devices and procedures is what this hearing is all about.

In mid-1994, the Department of Health and Human Services IG commenced an investigation of this problem by issuing 132 subpoenas to hospitals throughout the country. The Inspector General has

informed the Subcommittee that virtually all of the subpoenaed hospitals have billed Medicare for investigational devices, about half had provided evidence that they knew it was improper to do so, and a lesser percentage provided evidence that there was an attempt to cover up their actions.

The Subcommittee's investigation found that certain hospitals knew that what they were doing was in direct violation of Medicare policy but their ultimate goal was to get paid and at least in one hospital, patient consent forms were removed from the file so as to conceal the investigative nature of the surgery if audited.

Certain hospitals even continued to bill Medicare for these investigational procedures after receiving subpoenas from the Inspector General.

Today we will hear first from a witness inside the medical industry. He has assisted the Inspector General in their investigation and will provide first-hand knowledge of how these improper and fraudulent billings were accomplished.

He has filed a False Claims Act lawsuit, sometimes known as a Qui Tam suit. The court has ordered this case to remain under seal. Therefore, his identity will be protected during today's testimony.

We will also hear from the Inspector General and the Health Care Financing Administration, which administers the Medicare funds and sets the reimbursement policies. We have asked the Inspector General to discuss the findings as well as the expected goals of their investigation.

Each hospital asked by the Subcommittee about Medicare's policy on investigational devices claimed either that they did not understand or were not aware of Medicare's policy regarding reimbursement for investigational devices. We were also told that Medicare's policies were vague and unclear. Today the Director of Policy for HCFA will respond to these statements and you will hear he has a much different view of this issue.

Not all hospital billing departments found Medicare's policy on this issue unclear. Mr. Farrell Maier understood the policy and recognized the problem back in 1991, when he was director of the business office of Baptist Medical Center of Oklahoma. He wrote as clear and concise an explanation of Medicare's policy as anyone could expect. He stated simply that knowingly billing Medicare for non-approved devices was fraud.

In addition, Mr. Maier predicted that in 2 to 4 years, hospitals that billed would have a problem. Mr. Maier, your prediction was amazingly accurate.

And finally we will hear the testimony of three of the hospitals that, based on direct evidence from their own files, knew billing Medicare in these instances was wrong, but they did it anyway. Remember Medicare is first and foremost an honor system. It fundamentally relies on the integrity of the hospitals and other health care providers to initially and accurately bill Medicare.

If these hearings do nothing else but make it clear as to the importance of proper filing for reimbursement they are a success. I want to make it very clear to all parties concerned that last year's balanced budget amendment contained, at my insistence, some very tough enforcement procedures to address the issue of fraud

and abuse highlighted in the General Accounting Office high-risk report.

Clearly the majority of hospitals and health care providers work hard to supply needed medical treatment while operating within the scope of what the law allows. Unfortunately we know that with any large-scale government program there are those who will try to take advantage of the system. Medicare is certainly no exception.

We must ensure that the government agencies entrusted with the responsibility of administering these programs are vigilant in rooting out and preventing such fraud and abuse. This is an important part of the ongoing process to reform Medicare.

American taxpayers and their children are counting on us to ensure the continued effectiveness and integrity of the Medicare system.

In closing, let me say that there are no better hospitals than American hospitals. There are no better doctors than American doctors. Medicare beneficiaries deserve the best care that these hospitals and doctors can provide. That is our pledge to them and HCFA's basic responsibility. But to ensure such care, all parties—the doctors, the hospitals, HCFA and those of us in the Congress—must work together so that a system that delivers health care and handles the financing has the respect and support of all who come in contact with it.

PREPARED OPENING STATEMENT OF CHAIRMAN ROTH

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Those of us who are working to strengthen Medicare want to ensure that people eligible for Medicare are given the best care possible, and that the money will be there to pay for it. That is without question. My deep concern is that we are not doing enough to stop Medicare fraud where it starts. The answer is not just in more prosecutions, or trying to recoup money long after it's been paid. The answer is to administer this program properly, and hold accountable those who have the responsibility for the *oversight*, as well as the policies, of Medicare. In other words, put some teeth in the program, and make those who would abuse the system think twice before attempting to defraud Medicare. That is the only real way to begin to protect this vital program.

First, I want to make clear what this hearing is *not* about. It is *not* about Medicare patients receiving a lower quality of care. It is *not* about denying Medicare patients the latest state-of-the-art treatment. This hearing *is* about certain institutions who were able to evade the rules, resulting in, what the IG has estimated to be hundreds of millions of dollars in improper payments.

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In mid-1994, the Department of Health and Human Services Inspector General commenced an investigation of this problem by issuing 132 subpoenas to hospitals throughout the country. The Inspector General has informed the Subcommittee that virtually all of the subpoenaed hospitals had billed Medicare for investigational devices; about half had provided evidence that they knew it was improper to do so; and a lesser percentage provided evidence that there was an attempt to cover up their actions.

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SENATOR ROTH. Our first witness is an executive from inside the medical industry. This witness will be testifying from behind a screen and with the benefit of voice distortion to protect his identity. His identity will be protected during today's testimony because a court has ordered that the False Claims Act lawsuit that he has filed remain under seal.

It is my understanding that members of the media have already been advised as to those locations in the room where cameras will and will not be permitted during the course of this testimony in order to maintain security.

I see our friend from North Dakota is here. Do you wish to make an opening statement?

Senator DORGAN. No, Mr. Chairman.

Chairman ROTH. We will then proceed with the testimony. I put all the witnesses on notice that we swear in all witnesses who appear before this Subcommittee. In this instance, I will ask that the witness remain seated while I administer the oath.

Please, raise your right hand. Do you swear or affirm that the testimony that you give before the Subcommittee is the truth, the whole truth and nothing but the truth, so help you, God?

ANONYMOUS INDUSTRY WITNESS. Yes, I do.

Chairman ROTH. Please proceed with your statement.

TESTIMONY OF ANONYMOUS INDUSTRY WITNESS

ANONYMOUS INDUSTRY WITNESS. Good morning, Mr. Chairman.

I am submitting my formal written statement for the record. I would also like to give a brief opening statement if I may.

Can you hear me OK? I apologize for this distortion.

Chairman ROTH. Fine.

ANONYMOUS INDUSTRY WITNESS. Medicare abuse is rampant in the medical industry. Over the past 10 years I have witnessed the deliberate planning by many institutions and physicians to defraud the Medicare and Medicaid billing system. I have witnessed this fraud from inside the medical industry, in major hospitals, in medical device seminars and in operating rooms around the country.

What I have seen is an industry that believes it is not bound by the law and Medicare rules and regulations. That believes it is entitled to receive public funds by misusing Medicare billing codes, and at times, committing patient abuse.

Physicians go so far as to joke of the government's ineptness to investigate and prosecute fraud. The general feeling in the industry is that HHS will prosecute the small fish but it's too connected to the medical industry to prosecute the major abusers. The bigger the crime, the easier it is to get away with it.

I work in the medical field and am involved in the purchase and billing loop for hospitals' use of experimental medical devices. It is long been the rule of Medicare to exclude coverage for experimental medical devices.

In order to get reimbursed they must first receive marketing approval from the FDA. In order to receive marketing approval life-threatening devices, class III devices must be tested in humans and be proven safe and effective. This human experimentation process is called a clinical trial.

Clinical trials take place at approximately only 2 percent of the hospitals in the Nation for any given investigational device. Although these trials occur at only a small percentage of the hospitals and involve only a small percentage of the Medicare patient population, the use of experimental devices is extremely lucrative for the hospitals and the doctors involved.

They have a virtual monopoly in their geographic region for revenues that are generated from these new devices. This is high-profit business.

The lead doctors conducting the clinical trials are called clinical investigators. Many of these doctors are given stock, stock options, royalty contracts or cash by the experimental device manufacturers as incentive to use these devices as often as possible and to the exclusion of other devices and therapies.

These doctors are also the ones that are supposed to report objectively on the safety and effectiveness of the experimental devices to the FDA. Having positive reports by these clinical investigators submitted to the FDA can mean millions of dollars in profit to the companies involved.

Additionally, the clinical hospitals and doctors are positioned to corner the market for millions of dollars in patient referrals and revenues if the FDA approval is received.

When FDA approves a device, the price of the manufacturing company stock skyrockets. The clinical investigators with stock or stock options become wealthy overnight. The rush to reap financial rewards is tremendous incentive for doctors and hospitals to become participants in clinical trials. Despite the fact that these trials create a completely legitimate high-profit incentive, many in this segment of the medical industry are not satisfied with their high profitability and as a result deceive Medicare into paying for non-covered experimental devices.

This has resulted in public funding shifting away to pay for private industry's research and development. However, for each of these new beneficial devices developed there is even a greater number of device failures that truly jeopardize patient's safety. Approximately only one-third of all experimental devices are proven safe and effective and receive FDA approval for marketing.

The rest prove to be such a risk to patient's safety they are either withdrawn or rejected during the clinical phase. Additionally, private insurance recognizes the vast majority of experimental devices carry a greater risk in overall cost than FDA approved devices. Private insurance companies, once again, private insurance companies do not pay for unproven and untested devices in the experimental stage. They require that devices receive marketing approval by the FDA before they will pay for them.

So, in summary, only 2 percent of the hospitals in the Nation are involved for clinical trials for any given investigational device. The vast majority of experimental devices are never proven safe and ef-

fective. Most private insurance does not cover devices that have not been approved for marketing by the FDA.

As a result, Medicare's exclusion for experimental devices has not created a two-tier system discriminating against Medicare patients. What it has done is ensure patient safety standards must be met before hospitals and doctors using new technology can make these charges to taxpayers.

It is because of clinical hospitals and doctors abusing these rules that the Department of Health and Human Services Inspector General's investigation into this billing fraud began.

In the fall of 1993, I was contacted by the Inspector General's Office of Health and Human Services and by the Department of Justice to inquire into my knowledge of experimental device billing fraud. Because of my position in the medical field I was uniquely situated to learn of this type of fraud. I agreed to cooperate with the government and began using my contacts in the medical industry to uncover billing schemes that defraud Medicare into paying for experimental human trials.

As the investigation progressed from the fall of 1993 and into 1994, I became increasingly concerned about the risks the government was requiring me to take and that could jeopardize my career if it was to come out. Finally I was asked by the Office of HHS–IG and the Department of Justice to come forward as a whistleblower and encouraged to file a suit under the False Claims Act based on the false use of Medicare billing codes to submit claims for payment of non-covered devices and procedures.

I have seen quite a few billing schemes. One that has been uncovered is using pace-maker codes for implantable defibrillators, also known as AICDs. These experimental devices are consistently billed to Medicare as an AICD or implantable defibrillator. And implantable defibrillators are designed to sense an arrhythmia and they send a shock to return the heart to a normal rhythm. These are expensive device procedures averaging $40,000 to $60,000 each.

However, some of these devices are not as effective as previous devices that have already been approved by the FDA. The nature of the medical device industry is that it is extremely profitable. Accordingly, it is also very competitive. There are always attempts at new increments in technology going through clinical trials as different manufacturers, hospitals and doctors vie to capture the market place.

As a result, there are always new devices that have recently received FDA approval and are available for use with patients. It is not medically necessary for any given patient to have an experimental device implanted as opposed to some other new device that has recently been proven safe and effective and received FDA approval.

However, hospitals and physicians in clinical trials experiment on Medicare patients and aggressively bill Medicare for experimental AICDs or implantable defibrillators.

After being caught by Medicare for wrongfully submitting bills for experimental AICDs some hospitals began falsely billing these devices using other codes such as pacemaker codes to disguise their wrong doing. Others have openly discussed that there is a slight

risk of ever being caught and even slighter risk of ever being prosecuted.

As a result they continue to submit billings that hide the use of experimental devices. Even after being notified of this IG investigation in 1994, some hospitals and doctors were brazen enough to continue submitting fraudulent Medicare billings for these devices. I repeatedly witnessed hospital physicians scoff at the IG investigation stating that this was big business to the hospitals and doctors and they doubted that they would ever get caught so why bother to comply with the rules?

Another way they would hide the billing of experimental devices was to use or I should say to remove patient consent forms from the files. I am aware of instances where experimental device patient consent forms have been removed from patient files. The reasoning? Hospitals have patients sign a release for the risks associated with experimental devices and then bill Medicare as though the patient received an FDA-approved device.

Now, if audited, the patient consent form would be a red-flag to Medicare auditors. So that the auditors will be prevented from matching the Medicare billings and the related patient consent form which reveals the experimental device they simply pull the consent forms from the files.

Another method is the reimbursement balloon to disguise that they are using investigational devices. What I mean by this is that when experimental atherectomies and lasers are done—atherectomies are used in the coronaries, they are often called a rotor-rooter procedure—they have systematically been falsely claiming that they are doing angioplasty procedures when they are actually doing a rotor-rooter procedure. These experimental devices are intended to cut or remove plaque from the coronaries.

When the hospitals truthfully disclose to Medicare that these devices were experimental their claim for payment was denied. As a result, some hospitals and clinical investigators came up with the idea of re-invading the patient's body with a cheap angioplasty balloon off-the-shelf right after the experimental procedure. They run this balloon up the patient's artery, expand it, and take an X-ray for the patient's file in the event of a Medicare audit. A bill would then be submitted to Medicare hiding the experimental device procedure and instead claiming reimbursement for an FDA-approved angioplasty.

Physician training sessions sponsored by the medical industry promoted this falsification and it became known as the reimbursement balloon. This practice was so common place that some hospitals after the procedure was completed the physicians in the cath lab would joke that it is time for the reimbursement balloon and would re-invade the patient's body with a balloon solely for the purpose of creating a picture or X-ray and a paper trail to defraud Medicare.

This disgusting show of greed is not only Medicare abuse, this definitely is patient abuse.

Interestingly some of these catheter and laser companies have been shut down after conducting their clinical trials because other physicians in the health care community were unable to achieve the same procedural results.

Hospitals and doctors billing Medicare for experimental devices hide behind the blanket statement that experimental devices are the latest and greatest in technology. However, in a vast majority of the instances this simply is not true.

Another situation that I have come across is hospitals would bill Medicare as if they were using a brand-new device when, in fact, what they were doing was using a reused device or an old device. Ablation catheters and electrophysiology catheters are inserted in the patients to detect and treat electrical problems in the heart. These catheters are required by the FDA to be labelled for single use only. The reason is parts of these catheters are plastic. Blood and carcinogenic sterilants leach into plastic. However, some hospitals are violating the single use only rule requirement and are reusing the catheters from one patient to the next.

Patients are never informed that they are receiving an old, reused catheter with plastic parts that have been in numerous people before them. Although some hospitals attempt to resterilize the catheters between use, the sterilizing chemicals remain coated on the plastic catheters at dangerously high toxic levels.

After just a single reuse by hospitals, documented results is the catheters had coatings of ethylene oxide at toxic levels ranging 4 times to 12 times the maximum FDA levels. This has been well documented in the American Journal of Cardiology. It has been shown to cause cancer, birth defects, stomach, pancreatic cancer, leukemia and Hodgkin's disease, and ladies and gentlemen there is only one reason that hospitals are reusing these catheters and that is financial gain. There is no clinical benefit to doing this.

Some hospitals are reusing these catheters up to 20 times and billing them to patients as if they are using a new catheter. Reused catheters are not approved by the FDA and as such, are not reimbursable under Medicare rules. However, hospitals are charging Medicare and private insurance anyway as if they are using a brand-new catheter each time.

I formally brought the full specter of these and other fraudulent billing practices to the attention of the government in March of 1994 by filing a complaint under the Federal False Claims Act. Since that time, I have experienced first-hand the political power the medical industry wields in this country. After this blatant Medicare fraud was exposed, the medical industry responded with a massive political effort to retroactively excuse their fraud.

So that there is full disclosure, please understand that the False Claims Act provides that I will receive a percentage of the amounts recovered for the Treasury through the prosecution of this Medicare fraud. When the IG and the Department of Justice came forward and asked me to come forward in the context of a whistleblower they explained the concept of the False Claims Act and the fact that Medicare and other government contract fraud would go unchecked unless citizens would come forward.

I know that when my name becomes known my career is over. And, yet, I am one of the few people close enough to the evidence in the industry to know that this is all about money. big money. I am also one of the few people close enough to the evidence willing to publicly expose the facts about this pervasive fraud.

I am prepared to answer any of your questions that you may have.

[The prepared statement of Anonymous Industry Witness follows:]

PREPARED STATEMENT OF ANONYMOUS INDUSTRY WITNESS

Medicare abuse is rampant in the medical industry. Over the past 10 years, I have witnessed the deliberate planning by many institutions and physicians to defraud the Medicare and Medicaid billing system. I have witnessed this fraud from inside the medical industry: in major hospitals, in medical device seminars and in operating rooms around the country. What I have seen is an industry that believes it is not bound by the law and Medicare rules and regulations; that believes it is entitled to receive public funds by misusing Medicare billing codes and, at times, committing patient abuse. Physicians go so far as to joke of the government's ineptness to investigate and prosecute the fraud. It is the general feeling in the industry that HHS will prosecute the small fish, but is too connected to the medical industry to prosecute the major abusers. The bigger the crime, the easier it is to get away with.

I work in the medical field and am involved in the purchase and billing loop for hospitals' use of experimental medical devices. It had long been the rule of Medicare to exclude coverage for experimental and other devices that have not been approved for marketing by the FDA. In order to receive FDA marketing approval, life-threatening (Class III) devices must be tested in humans and be proven safe and effective. This human experimentation process is called a "clinical trial." Clinical trials take place at approximately only 2 percent of the hospitals in the Nation for any given investigational device. Although these trials occur at only a small percentage of the hospitals and involve only a small percentage of the Medicare patient population, the use of experimental devices is extremely lucrative for the hospitals and doctors involved. They have a virtual monopoly in their geographic region for revenues to be generated from a new device. This is a high profit business.

The lead doctors conducting the clinical trials are called "clinical investigators." Many of these doctors are given stock, stock options, royalty contracts or cash by the experimental device manufacturers as an incentive to use the devices as often as possible and to the exclusion of other devices or therapies. These doctors are also the ones who are supposed to report on the safety and efficacy of the experimental device to the FDA. Having positive reports by these "clinical investigators" submitted to the FDA can mean millions of dollars in profit to the companies involved. Additionally, the clinical hospital and doctor are positioned to corner the market for millions of dollars in future patient referrals and revenues if the FDA approval is received. When FDA approves a device, the price of the manufacturing company's stock skyrockets. The "clinical investigators" with stock or stock options become wealthy overnight. The rush to reap financial rewards is tremendous incentive for doctors and hospitals to become participants in clinical trials. Despite the fact that these trials create a legitimate high profit incentive, many in this segment of the medical industry are not satisfied with their high profitability and, as a result, deceive Medicare into paying for non-covered experimental devices. This has resulted in public funding shifted away to pay for private research and development. However, for each beneficial new device developed, there are an even greater number of device failures that jeopardize patient safety. Approximately only one-third of experimental devices are proven safe and effective, receiving FDA approval for marketing. The rest prove to be such a risk to patient safety that they are either withdrawn or rejected during the trial phase.

Additionally, private insurance recognizes that the vast majority of experimental devices carry a greater risk and overall cost than do FDA approved devices. Private insurance companies do not pay for unproven and untested devices in the experimental stage. They require that medical devices receive marketing approval by the FDA before being covered by insurance.

In summary, only 2 percent of the hospitals in the Nation are involved in clinical trials for any given investigational device. The vast majority of experimental devices are never proven safe and effective. Most private insurance does not cover devices that have not been approved for marketing by the FDA. As a result, Medicare's exclusion for experimental devices has not created a two-tiered system discriminating against Medicare patients. What it has done is assure that patient safety standards must be met before hospitals and doctors using new technology can bill the charges to the taxpayers. It was because of clinical hospitals' and doctors' abuse of these rules that an HHS–IG investigation into this billing fraud began.

In the fall of 1993, I was contacted by the Inspector General's Office of Health and Human Services and by the Department of Justice to inquire into my knowledge of experimental device billing fraud. Because of my position in the medical field, I was uniquely situated to learn of this type of fraud. I agreed to cooperate with the government and began using my contacts in the medical industry to uncover billing schemes that defraud Medicare into paying for experimental human trials.

As the investigation progressed from the fall of 1993 and into 1994, I became increasingly concerned about the risks the government was requesting me to take that would jeopardize my career. Finally, I was asked by the Office of HHS–IG and the Department of Justice to come forward as a whistleblower and encouraged to file a suit under the Federal False Claims Act based on the false use of Medicare billing codes to submit claims for payment of non-covered devices and procedures.

Among the billing schemes I have witnessed are:

Pacemaker Codes and AICD's

One of the experimental devices consistently billed to Medicare is an Automatic Implantable Cardiac Defibrillator (AICD). Implantable defibrillators are designed to sense an arrhythmia and send an electrical shock to return the heart to a normal rhythm. These are expensive device procedures, averaging $40,000–$60,000 each.

However, some of these experimental devices are not as effective as previous devices that have already been FDA approved. The nature of the medical device industry is that it is extremely profitable. Accordingly, it is also very competitive. There are always attempts at new increments in technology going through experimental trials, as different manufacturers, hospitals and doctors vie to capture the marketplace. As a result, there are always new devices that have recently received FDA approval and are available for use with patients. It is not medically necessary that any given patient have an experimental device implanted, as opposed to some other new device that has recently been proven safe and effective and received FDA approval.

However, hospitals and physicians involved in clinical trials experiment on Medicare patients and aggressively bill Medicare for experimental AICDs. After being caught by Medicare in wrongfully submitting billings for experimental AICDs some hospitals began falsely billing these experimental devices as pacemakers. Others have openly discussed that there is slight risk in ever being caught and even slighter risk in ever being prosecuted. As a result, they continue to submit billings that hide the use of experimental devices.

Even after being notified of this HHS–IG investigation in 1994, some hospitals and doctors were brazen enough to continue submitting fraudulent Medicare billings for these devices. I repeatedly witnessed hospital physicians scoff at the HHS–IG investigation, stating that this was big business for the hospitals and doctors and they doubted that they would ever get caught so why bother to comply with the coverage rules?

Removing Consent Forms from Patient Files

I am aware of instances where experimental device patient consent forms have been removed from patient files. The reasoning: Hospitals have patients sign a release for the risks associated with experimental devices, and they then bill Medicare as though the patient had received an FDA approved device. If audited, the patient consent form would evidence the fraud to Medicare. So that HCFA auditors will be prevented from matching the Medicare billing and the related patient consent form, which reveals the experimental device, the consent forms are removed from the files.

The Reimbursement Balloon

Experimental atherectomies and lasers have been systematically billed by falsely claiming they were angioplasty balloon procedures. These experimental devices are intended to cut or remove plaque from the arteries. Whenever the hospitals truthfully disclosed to Medicare that these devices were experimental, their claim for payment was denied. As a result, some hospitals and "clinical investigators" came up with the idea of re-invading the patient with an angioplasty balloon after the experimental procedure. They would run the balloon up into the patient's artery, expand it and take an X-ray for the patient's file in the event of a Medicare audit. A bill would then be submitted to Medicare, hiding the experimental device procedure and instead claiming reimbursement for an FDA-approved angioplasty. Physician training sessions sponsored by the medical industry promoted this falsification as the "reimbursement balloon." This practice became so common place at some hospitals that, after the experimental device procedure, the physicians in the operating room would joke that it was "time for the reimbursement balloon" and would re-

invade the patient with a balloon solely for the purpose of creating an X-ray and paper trail to defraud Medicare.

This disgusting show of greed is not only Medicare abuse; it is patient abuse.

Interestingly, some of these atherectomy catheter and laser companies have been shut down after conducting their clinical trials because other physicians in the health care community were unable to achieve the same procedural results that the "clinical investigators" reported to the FDA. As an example, one atherectomy catheter company was recently shut down due to patient injuries from its product. Another example is a laser angioplasty catheter touted by clinical investigators as the latest and greatest device for removal of plaque from clogged arteries. This device actually resulted in so many patient complications that the health care community has refused to subject patients to the procedure and the manufacturer has closed down.

In fact, the New England Journal of Medicine has reported that the standard procedure of FDA approved balloon angioplasty is safer, results in less complications and is more effective than the experimental atherectomy procedures that were fraudulently billed to Medicare. This multi-center randomized study showed that atherectomy procedures resulted in a higher risk of patient death and a higher risk of needing emergency open heart surgery due to complications from the procedure, as compared to the standard balloon angioplasty procedure. (New Eng. Jnl. of Medicine 1993; Vol. 329: 221–227).

Hospitals and doctors billing Medicare for experimental devices hide behind the blanket statement that experimental devices are the latest and greatest in technology. However, in the vast majority of instances, this simply is not true.

Billing Medicare for "New" Devices that are In Fact "Re-Used" Devices

Ablation and electrophysiology (EP) catheters are inserted into patients to detect and treat electrical problems in the heart. These catheters are required by FDA to be labeled "Single Use Only." The reason: Parts of these catheters are plastic. Blood and carcinogenic sterilants leach into plastic. However, some hospitals are violating the "single use only" requirement and are re-using these catheters from patient to patient. Patients are *never* informed they are receiving a re-used catheter with plastic parts that have been used in numerous people before them.

Although hospitals attempt to re-sterilize the catheters between use, the sterilizing chemicals remains coated on the plastic catheters at dangerously high toxic levels. After just a single re-use by hospitals, the documented result is that catheters have coatings of carcinogenic Ethylene Oxide at toxic levels ranging from 4 times to more than 12 times the FDA maximum level. This carcinogen can bond genetically to DNA and causes birth defects, stomach and pancreatic cancer, leukemia, Hodgkin's disease and other illnesses. (Am. Jnl. of Cardiology 1994; Vol. 74: 1173–1175). Patients are unknowingly and needlessly being exposed to these health risks for one reason, and one reason only: Financial gain by the hospitals. Some hospitals are re-using the catheters up to 20 times and billing them as new.

Re-used catheters are not approved for marketing by the FDA and, as such, are not reimbursable under Medicare. However, hospitals are charging Medicare and private insurance anyway as if they were using new catheters as required by FDA labeling.

I formally brought the full specter of these and other fraudulent billing practices to the attention of the government in March, 1994, by filing a complaint under the Federal False Claims Act. Since that time I have experienced first-hand the political power the medical industry wields in this country. After this blatant Medicare fraud was exposed, the medical industry responded with a massive political effort to retroactively excuse their fraud. So that there is full disclosure, please understand that the False Claims Act provides that I will receive a percentage of the amounts recovered for the Treasury through the prosecution of this Medicare fraud. When the HHS–IG and the Department of Justice asked me to come forward in this context as a whistleblower, they explained the concept of the False Claims Act and the fact that Medicare and other government contract fraud would go unchecked without insiders like me coming forward.

I know that when my name becomes known, my career is over. Yet, I am one of the few people close enough to the evidence in the industry to know that this is all about money. Big money. I am also one of the few people close enough to the evidence willing to publicly expose the facts about this pervasive fraud.

I am prepared to answer any of your questions.

Chairman ROTH. I want to be perfectly clear about any personal financial gain you might receive from this matter. You mentioned that you have filed a lawsuit against 132 hospitals that received

the IG subpoenas. Is it not true that if the suit is successful you will participate in the award?

ANONYMOUS INDUSTRY WITNESS. Yes.

Chairman ROTH. Why would the HHS–IG have suggested that you file a Qui Tam lawsuit in this matter?

ANONYMOUS INDUSTRY WITNESS. I was becoming increasingly concerned about my career the more I assisted the IG. If my name was to come out, my career would be over. I was asking the government lawyers what type of protection there would be for myself and the government lawyers mentioned the witness protection program and the Federal False Claims Act. And since my life was not in immediate danger they recommended and explained to me about the Federal False Claims Act. They then gave me the names of three private attorneys and told me to go and seek counsel.

They said without individual citizens coming forward there would be—and especially in this case—it would have been very hard for them to collect the money that had been stolen from the Federal Treasury.

Chairman ROTH. Let me ask you this, why should not Medicare have paid for the development of these devices?

ANONYMOUS INDUSTRY WITNESS. The way it was explained to me by the Department of Justice and the Health and Human Services Department is that Medicare money is for patient care, not for human experimentation and not to subsidize private industry's research and development costs.

The industry we are talking about is a $57 billion industry that is growing at approximately 50 percent a year. It is extremely profitable. They do not need to be at the Federal trough. They can and should pay for their own research and development just like every other major industry in the high-tech area in the United States of America.

And also a point, private insurance does not pay for experimental devices. Why should taxpayers pay for devices that have not yet been proven safe and effective?

Chairman ROTH. Would the patient normally pay when they participate in a clinical trial such as we are discussing?

ANONYMOUS INDUSTRY WITNESS. Senator Roth, I have no knowledge of a patient ever having to pay for an investigational device or procedure.

Chairman ROTH. You mentioned the removal of patient consent forms from the patient files. Explain why this would be done.

ANONYMOUS INDUSTRY WITNESS. Well, first of all, a patient consent form is used to explain to the patient that there is a higher degree of risk associated with an experimental procedure. But to a Medicare auditor this is a red flag that an un-reimbursable experimental procedure has been done. By removing this consent form, it destroys the paper trail and could throw off Medicare auditors.

Chairman ROTH. You described the so-called reimbursement balloon. Are you saying that an entirely unnecessary invasive procedure was being performed on patients for the purpose of billing Medicare?

ANONYMOUS INDUSTRY WITNESS. Yes, sir, I am. After, for example, a successful rotor-rooter procedure, the cardiologist would ask a technician to pull the cheapest balloon off the shelf in the cath

lab. They would then re-invade the patient, run the balloon up into the coronaries, take an X-ray for the patient's file for the sole purpose of creating a paper trail to submit this as an angioplastic procedure.

That way if they are audited there's a picture of the angioplasty balloon. Now, one thing to understand, the comment was also often made that $500 for an angioplasty balloon is a small price to pay to guarantee reimbursement for a $15,000 experimental procedure.

Chairman ROTH. Were you ever present when one of these procedures was being performed?

ANONYMOUS INDUSTRY WITNESS. Yes. I was present in dozens of centers with dozens of physicians.

Chairman ROTH. Can you explain what you meant when you referred to physician training centers advocating this outrageous billing practice?

ANONYMOUS INDUSTRY WITNESS. Well, physician training sessions are set up by the manufacturers to bring physicians in to train them on new experimental procedures. One of the first questions that usually comes up is how do we get reimbursed for the experimental procedures?

The story would then be told of the reimbursement balloon. Often it would bring nervous laughter from the physicians in the group and often there would be also a group that showed disgust by the thought of it. But, obviously, the evidence showed that some physicians went back to their hospitals and did this practice.

Chairman ROTH. Did you ever personally attend one of these training sessions?

ANONYMOUS INDUSTRY WITNESS. Yes, sir, I did. I might also add that I have attended company sponsored training sessions where major patient catastrophes have happened. I was at one where while they were trying to train physicians on how to do the new rotor-rooter procedure the device unraveled basically shredding the patient's coronary. They, at that point, rushed the patient to surgery. The patient, I am afraid to say, died 2 days later.

Chairman ROTH. From your unique position within the industry has this IG investigation made any impact on curbing abuse of the Medicare system?

ANONYMOUS INDUSTRY WITNESS. Mr. Chairman, when the investigation first started it did have an impact. But once the hospitals saw that they were successful in wielding their political power, one comment was made to me it is like the Department of Health and Human Services called us out into the alley but then were afraid to show up.

Chairman ROTH. Senator Dorgan?

OPENING STATEMENT OF SENATOR DORGAN

Senator DORGAN. Thank you, Mr. Chairman.

Let me ask unanimous consent to include in the record a prepared opening statement.

Chairman ROTH. Without objection.

[The prepared opening statement of Senator Dorgan follows:]

PREPARED OPENING STATEMENT OF SENATOR BYRON L. DORGAN

Thank you, Mr. Chairman, and good morning. I would like to begin by saluting you for the work that you have done in bringing this investigation this far. This is a complex issue of possible Medicare fraud that we are looking into this morning, and I appreciate your efforts to bring this matter before the public and to try to learn how we can avoid similar problems in the future.

Today's hearing focuses on what can go wrong at the cutting edge of research on pacemakers and other advanced cardiac devices. When a manufacturer develops a new pacemaker, that device must undergo clinical trials before it is approved by the Food and Drug Administration. And Medicare, the Federal Government's health insurance program for the elderly, will only pay hospitals for FDA-approved procedures and devices. Today's hearing looks at instances where hospitals have allegedly billed the Medicare system for non-FDA-approved devices—and Medicare has paid, perhaps as much as $1 billion over 5 years.

This morning the Subcommittee will hear evidence from an industry witness suggesting that:

—the Health Care Financing Administration's policy on reimbursing investigational devices was clear and unambiguous;
—certain hospitals billed HCFA for investigational devices despite *knowing* the policy, and therefore appear to have committed fraud;
—some hospitals involved in clinical trials actually misdescribe the operation for which they seek reimbursement, falsely billing Medicare for FDA-approved devices when the devices are really investigational; and
—some hospitals try to cover up their behavior by suppressing incriminating evidence from patients' files.

We will also hear from Mr. Farrell Maier, who used to work for the Baptist Medical Center in Oklahoma City. Mr. Maier is a good guy in this story—when he came under pressure to approve billing Medicare for investigational devices, he fought against it. He also told a Medicare auditor that fraud seemed rampant in this area. However, as he will tell us, there was little response to his warning.

The testimony we will hear raises important questions for our health care system.

First, medical device manufacturers pay doctors to conduct clinical trials involving cutting-edge products. Does this create an improper incentive for doctors to recommend certain expensive procedures? If a doctor is both very influential in a hospital and an innovator in cardiac device development, should that doctor be permitted to make his own device a standard treatment in his cardiac department?

One could also conclude from today's testimony that bad actors are confident they will not get caught, and that fraud is therefore rampant. Is this truly the case? How confident can Congress and the taxpayers be that our Medicare system is fraud-proof—or at least fraud-resistant? Are there enough resources and personnel for Medicare audits, for example?

Lastly, as the Governmental Affairs Committee knows from previous work that my colleagues and I have done, the Federal Government does not now do a good job of collecting fines and penalties. Given this record, how much of the improper reimbursements to hospitals—up to $1 billion in total—will be recovered?

These are some of the questions that I will have in mind as this hearing goes forward, Mr. Chairman. Let me summarize by saying that the taxpayers are entitled to the efficient and legal use of their health care dollars. this hearing should shed light on how we fall short of that goal, and what kind of progress we need to make.

Senator DORGAN. I decided not to give it. I wanted to hear the witness. I appreciate very much the witness coming forward and testifying this morning.

I recognize that if you investigated virtually any industry you would likely find some fraud. But the story you tell bothers me a lot because of the culture you describe.

I want to ask you about that just a bit. You just finished responding to a question by Senator Roth about the catheter procedure using a so-called rotor-rooter, as you describe it. You indicated that the doctors would follow that by entering with a balloon catheter in order to get reimbursement and take X-rays, which they would then put in the file, I assume, as documentation.

You indicated that you have seen that done at dozens of centers by dozens of physicians or you know of that being done?

ANONYMOUS INDUSTRY WITNESS. Yes, sir.

Senator DORGAN. Which? You have seen it or know of it?

ANONYMOUS INDUSTRY WITNESS. I have seen it directly.

Senator DORGAN. And that, I assume one could make a reasonable case that that represents fraudulent billing.

ANONYMOUS INDUSTRY WITNESS. Yes, sir.

Senator DORGAN. Deliberately fraudulent billing?

ANONYMOUS INDUSTRY WITNESS. Definitely.

Senator DORGAN. And in the dozens of centers where you have seen it and the dozens of physicians who have performed it, are you aware of potential criminal actions being brought against these centers or the physicians?

ANONYMOUS INDUSTRY WITNESS. I personally do not know that, sir.

Senator DORGAN. You describe here a culture, however, that suggests that those who engage in this catheter procedure do not feel there is great risk of their fraud being detected. You suggest that they kind of grin to each other about it, or that they realize that well, we are cheating here but the fact is nobody is going to catch us anyway. Is that the culture that you describe?

ANONYMOUS INDUSTRY WITNESS. That is a good representation of the culture. Actually to relate a story, one physician during a procedure mentioned that physicians represent the top 1 percent of the intellect in the United States of America and together with the American Medical Association and the American Hospital Association no government bureaucrats are going to tell us what to do, we will kill and are successful in killing this investigation. And we will tell them when and what to do.

That is the general culture that you are dealing with.

Senator DORGAN. You indicated, in response to one of the final questions that Senator Roth asked, that political power was at work here. You are telling us that doctors or hospitals have suggested that they would wield sufficient political power to squelch or kill any investigation. Can you amplify on that? What are you referring to?

ANONYMOUS INDUSTRY WITNESS. I am referring to the American Medical Association, the American Hospital Association and their general campaign and lobbying efforts to basically put pressure on HHS to change the rules and to get them to back off on the investigation. They had various congressmen and political figures write letters which would throw them into complete array and have to respond.

Senator DORGAN. Let me ask you about new medical devices and the clinical trials. You have raised an issue that I had not even thought about previously, but when you described it in your statement, it just occurred to me that we may have a fundamentally improper situation.

You spoke about a manufacturer of a cardiac device that sends that device out for clinical trials. The manufacturer then bestows upon doctors who will be conducting the trials stock ownership in the manufacturer. It seems to me, on its face, that such a situation presents a massive conflict of interest.

You described this conflict in your testimony, but you did not indicate how widespread you think it is. Now, we could probably, through some investigation, determine how widespread this conflict is. But give me your impression. Is this a widespread practice?

ANONYMOUS INDUSTRY WITNESS. This is very widespread. In the example of the rotor-rooter procedure one clinical investigator walked away with over $12 million in stock options once there were positive reports given to the FDA and they received FDA approval. It is very pervasive.

Senator DORGAN. When you say, very pervasive, you are saying that a substantial percentage of——

ANONYMOUS INDUSTRY WITNESS. Yes, I am. Also I think a thing to be cognizant of and that you are hitting on this is, in essence, these people are the gatekeepers. These people are the people that are supposed to determine whether these devices are safe and effective for the general public. How can they be objective when, if the device succeeds, they become millionaires; if it fails their work is for naught.

Senator DORGAN. Mr. Chairman, you are aware that much of the government is now operating under a continuing resolution, which regrettably cuts funding for the Office of Inspector General at the Department of Health and Human Services. The very government auditors and investigators who are trying to detect and fight health care fraud and abuse have seen their ability to investigate, their ability to audit substantially hampered.

I think we all would hope that the Congress restores this funding, because I think the testimony here describes some very serious problems. I do not know how widespread these decisions practices are. But when I hear you describe the culture and then I hear you describe the specifics and I hear you say that you have witnessed in dozens of centers with dozens of physicians what appears to be deliberate fraud, I start worrying.

I do not want to paint all physicians that way because there are a lot of wonderful people in this country in the industry providing daily care to people in wonderful ways. And there are a lot of wonderful hospitals. But as in any business or any occupation, politics, medicine or others, this sort of thing can occur. It is disgusting. It just makes you sick that this sort of thing goes on.

And it is very important to move aggressively where we find fraud. When we discover that people in this industry think they can grab hold of the Medicare system and squeeze it to enrich themselves, and when we learn that they do so by incurring risks to Medicare patients at substantial cost to the taxpayers, we have a responsibility to pursue this aggressively.

Where fraud exists we ought to prosecute it aggressively. We ought to send signals across this country you cannot do this. If you do it you are going to get hurt quickly by the criminal justice system because we will not allow it.

Now, I do not know you. I have never met you. I do not know anything about you. But I think your contribution with this statement is a significant contribution to this Committee's work. This is precisely the kind of thing that this Committee needs to investigate. We need to produce some results. With the amount of money that this country spends in the Medicare program, with the

trust that senior citizens and others have in us to make sure this program works well, we cannot countenance this kind of behavior.

I know it was probably difficult for you to do. But I think you provide a service by telling us what you know of the practices in the circumstances as you describe them.

Mr. Chairman, thank you.

Did you have another comment?

ANONYMOUS INDUSTRY WITNESS. Just a comment. I would like to reiterate what you said. First of all, the attitude and the culture that I was projecting represents only about 2 percent of the physician population.

The vast majority are doing a great service to the public. They are helping the sick. They work hard. We are talking about 2 percent that are involved in these clinical trials. But this is a very high profit, highly visible area with a lot of dollars. But once again, a very few, there is only a few bad apples in each of these hospitals. What we are talking about is a very small number overall.

Senator DORGAN. But the point is that those bad apples can spoil the image of every other doctor and hospital in this country that daily tries to provide good service.

ANONYMOUS INDUSTRY WITNESS. That is correct.

Senator DORGAN. And we have a responsibility to find fraud and prosecute it aggressively where it exists.

ANONYMOUS INDUSTRY WITNESS. That is correct.

Chairman ROTH. That, of course, is the purpose of this hearing today. As I said earlier, it is critically important if this system of Medicare is to work that claims of reimbursement be honest and forthright. We must develop the kind of culture that ensures that every health care provider fully understands that.

One of my concerns is, as you had mentioned, the conflict of interest that appears to exist in using physicians and others as consultants in these clinical tests. Are there any rules or regulations that you are aware of that have been issued by HCFA circumscribing, forbidding or in any way regulating this practice?

ANONYMOUS INDUSTRY WITNESS. I, personally, would not know, to tell you the truth, what the rules and regulations are. I have been told by the IG that some State employees are not supposed, from an ethics standpoint, to take money from vendors for using their product.

Chairman ROTH. But I am asking from the Federal standpoint?

ANONYMOUS INDUSTRY WITNESS. No. I have no knowledge of that, of those type of rules.

Chairman ROTH. Senator Levin?

OPENING STATEMENT OF SENATOR LEVIN

Senator LEVIN. Thank you, Mr. Chairman.

You have described two different kinds of abuse. One is the Medicare fraud, reimbursement for procedures that are not reimbursable. You have also described patient abuse.

And I want to focus first on the patient abuse issue because what you have told us is that in dozens of places, dozens of doctors have performed operations or procedures which are invasive without any purpose except to provide a paper trail of some kind for Medicare reimbursement and you have personally witnessed that.

ANONYMOUS INDUSTRY WITNESS. That is correct.

Senator LEVIN. And we are going here, as much as we are deeply concerned about Medicare reimbursement and fraud, you are going way beyond that to talk about endangering a patient's life and physical well being.

ANONYMOUS INDUSTRY WITNESS. That is correct.

Senator LEVIN. Now, have you provided to the Subcommittee the list of those dozens of clinics I think you said, or hospitals and dozens of doctors that have re-invaded patients with balloons after the rotor-rooter procedure was finished?

ANONYMOUS INDUSTRY WITNESS. No. I have not provided the specifics. I would be glad to do so in private so it does not divulge my identity. Plus, I am under court order not to specify any individual defendants because the case is still under seal and investigation.

Senator LEVIN. I see. So that a court has ordered you not to disclose even in confidence to this Subcommittee the names of those clinics and doctors?

ANONYMOUS INDUSTRY WITNESS. In private I would be glad to.

Senator LEVIN. Will you do that?

ANONYMOUS INDUSTRY WITNESS. Definitely, definitely.

Senator LEVIN. What you have seen on these dozens of occasions then is after the experimental procedure was completed then the doctor would go in with the——

ANONYMOUS INDUSTRY WITNESS. Cheapest balloon on the shelf.

Senator LEVIN [continuing]. Cheapest balloon on the shelf. And then the consent form was removed from the file so that the Medicare auditor would not be able to see that there was, in fact, an experimental procedure?

ANONYMOUS INDUSTRY WITNESS. That is correct.

Senator LEVIN. Was there a new consent form put into the file to take its place?

ANONYMOUS INDUSTRY WITNESS. No.

Senator LEVIN. Well, would not the auditor then see the absence of a consent form and then be suspicious?

ANONYMOUS INDUSTRY WITNESS. No. Basically when you have a consent form in a medical file it directs the auditor what files to go into. As with any audit, they do not audit every medical file. They grab maybe 2 or 3 percent of the overall files. And a patient consent form is a good flag that this may be an un-reimbursable procedure that they charged for.

Senator LEVIN. But if the auditor in that file that he happens to grab does not see a consent form is that not a red flag? Is that not a little bit like the hound of the Baskerville not barking?

ANONYMOUS INDUSTRY WITNESS. Well, here is the situation. If they had done a reimbursement balloon and they had a picture of the angioplasty balloon in the file they would just think an angioplasty had been done.

Senator LEVIN. You put a lot of emphasis on a consent form on an experimental file being a flag to an auditor. My question is would not the absence of any consent form also be a flag?

ANONYMOUS INDUSTRY WITNESS. No. Because they are assuming that these are FDA approved procedures that are being done, otherwise, the hospital would not have billed.

Senator LEVIN. Now, the purpose of the experimental procedure I assume is to see whether or not the experiment does some good for the patient.

ANONYMOUS INDUSTRY WITNESS. That is correct.

Senator LEVIN. Now, if after the experiment is done a balloon is then put into the same artery does that not ruin the value of the experiment?

ANONYMOUS INDUSTRY WITNESS. Exactly. Especially if they were to truly do the procedure then what caused the long-term benefits? Was it the balloon or the rotablator?

Senator LEVIN. Are you saying that they do not do the balloon procedure or they do?

ANONYMOUS INDUSTRY WITNESS. No. They do not. They just blow up the balloon and take a picture because that problem has already been fixed.

Senator LEVIN. I see. They do not put it in the artery?

ANONYMOUS INDUSTRY WITNESS. Yes, they do to take the picture.

Senator LEVIN. Well, if they put it in the artery does that not ruin the experiment?

ANONYMOUS INDUSTRY WITNESS. If they expanded and cracked and tear the vessel, yes. But if they—they usually just under-inflate the balloon just for the sake of getting a picture not for actually cracking or fracturing the lesion in the vessel or the blockage in the vessel.

Senator LEVIN. But my question is, if they inflate the balloon inside the artery does that not damage the experiment because there would not be certainty as to whether or not any correction is the result of either the experimental device or the balloon?

ANONYMOUS INDUSTRY WITNESS. If they used higher pressure, yes. If they used a minimal pressure, no.

Now, the danger is——

Senator LEVIN. Which did they use in the dozens of times that they used——

ANONYMOUS INDUSTRY WITNESS. Usually low-inflation pressure. The danger is, though, that when they re-invade a patient with a second time and cross a lesion they have a chance of causing a flap or a tear at the repair site. And that is something that generally clinically should never be done.

Senator LEVIN. They are endangering their patients.

ANONYMOUS INDUSTRY WITNESS. Yes. They are exposing the patients to needless risk that they need not expose them to.

Senator LEVIN. Now, going back just to the consent form for a minute, I am sorry, is there a green light here?

Chairman ROTH. Go ahead.

Senator LEVIN. OK. On the reimbursement area, I take it that patients are not informed as to the double procedure?

ANONYMOUS INDUSTRY WITNESS. That is correct.

Senator LEVIN. And you are aware that you saw this being done because you have some kind of a background where you know what is going on. Are you a—I do not know your identity and I am not trying to get it—do we know what profession? Whether or not the witness has a medical background or not? Is that public knowledge? I have never seen the witness before and I do not want to get into any area I should not.

Do we know whether or not the witness or is it public whether or not the witness has professional medical background?

Chairman ROTH. That is not public information.

Senator LEVIN. OK. Would you agree that the experiment would have less value if balloons were inserted after the experimental procedure were completed?

ANONYMOUS INDUSTRY WITNESS. I do not think I should comment. I just do not know the correct answer. It would vary from patient to patient.

Senator LEVIN. Now, in these cases, these dozens of cases that you have witnessed hospitals and physicians doing this, it particularly was relating to the balloon, would the hospitals and doctors have to be working in collusion or in cahoots in order for this to work?

ANONYMOUS INDUSTRY WITNESS. Not necessarily.

Senator LEVIN. It would be the doctor could be using this second procedure without the hospital even being aware of it?

ANONYMOUS INDUSTRY WITNESS. Yes, they could be but it was such a common joke within the procedure room that all the staff knew and the people that fill out the billing forms definitely knew that the reimbursement balloon was the only way they were going to get reimbursed especially after being denied. If the hospital was denied because they told the government they were doing an experimental procedure and then they were joking, well, we will just put it through on the reimbursement balloon and charge it as an angioplasty.

Senator LEVIN. Would this action of these dozens of doctors of re-invading patients constitute unethical, indeed, perhaps criminal activity on the part of a doctor? To take the risk that you described, where the re-invasion could actually cause damage, would that not be a violation, at least, of the doctor's license and the code of ethics?

ANONYMOUS INDUSTRY WITNESS. I would not know about the legal ramifications. But I do know ethically it is disgusting.

Senator LEVIN. You know enough about medical ethics to know whether or not the re-invasion of a patient's body with a medical procedure which is not indicated would violate the code of medical ethics?

ANONYMOUS INDUSTRY WITNESS. I would think so, yes.

Senator LEVIN. And then what you are telling the Subcommittee is that you have, personally, witnessed in these dozens of cases doctors that are doing this in a way which will jeopardize their own licenses since a violation of medical ethics will jeopardize any doctor's licenses and that the reason they are doing this is in order to get the Medicare reimbursement?

ANONYMOUS INDUSTRY WITNESS. That is correct. And you have got to remember the physician in the cath lab or the operating room is king. It is not a democracy in an operating room or a cath lab.

Senator LEVIN. I think I just had one additional question, Mr. Chairman, if I have time. Have you submitted to the Subcommittee the list of the doctors who have the stock and stock options and royalty contracts with the device manufacturers for devices which

they are using? Is that something you have already submitted or will you submit to the Subcommittee?

ANONYMOUS INDUSTRY WITNESS. I have not submitted a complete list but we will do it if you would like.

Senator LEVIN. Yes. I think that we should have that also.

Thank you and thank you, Mr. Chairman.

ANONYMOUS INDUSTRY WITNESS. Thank you.

Chairman ROTH. Prior to the exit of the witness, I direct that all cameras be turned to—Senator Dorgan has an additional question.

Senator DORGAN. Mr. Chairman, I wanted to ask just an additional question. The experimental devices that you have discussed are, I think, exclusively cardiac ones. Is there any reason to believe that experimental devices used in other areas of medicine are subject to the same kind of problems—fraudulent billing practices?

Why do we only hear from you about the cardiac issues?

ANONYMOUS INDUSTRY WITNESS. I have direct knowledge about the cardiac areas. We have also learned in our investigation or the investigation of the government has learned that this is going on in other areas, too, and is being investigated.

Senator DORGAN. But your direct knowledge deals with the——

ANONYMOUS INDUSTRY WITNESS. Cardiac.

Senator DORGAN [continuing]. Dealing with the heart, is that correct?

ANONYMOUS INDUSTRY WITNESS. That is correct.

Senator DORGAN. To touch on the issue raised by Senator Levin, the underlying issue here, as I understand your testimony, is greed. Having used an experimental device for which Medicare will not reimburse, some doctors then go back in with the angioplasty balloon and reopen the artery, in order to use a $500 device and achieve a $15,000 reimbursement from the government in a fraudulent way.

ANONYMOUS INDUSTRY WITNESS. That is correct.

Senator DORGAN. And that exposes the patient to an insertion in the artery of another device?

ANONYMOUS INDUSTRY WITNESS. That is correct.

Senator DORGAN. And the culture of this did not bother physicians in the surgical suites where you witnessed this?

ANONYMOUS INDUSTRY WITNESS. As I was mentioning in my opening statement, there is such great financial incentive to corner the market for any new technology that I guess they weighed one against the other and decided which direction they were going to go.

You know, please, do not get me wrong. There are some new devices that are great advances over older approved devices. Although there is also a great many that have no benefit and then there is another group that are extremely dangerous that never make it out of clinicals.

Up front, we do not know which device is going to be safe and effective. That is what clinical trials and the FDA is in place for.

Senator DORGAN. Well, you are right. In order to find new devices there must be experimentation and trials. The issue here is fraud.

ANONYMOUS INDUSTRY WITNESS. Correct.

Senator DORGAN. It really breaks one's heart to hear the testimony. I have been in these cath labs with a member of my family and had tragic results in the operating room from heart surgery. It just makes me furious and also, in another way, it breaks my heart to hear about the culture you describe.

I understand again and it is important probably to reemphasize we are talking about a minority, not a majority, of providers. But it seems to me this sort of thing has to be stopped and fraud has to be prosecuted as aggressively as possible.

Mr. Chairman, thank you very much.

Senator LEVIN. Mr. Chairman, I just had one question.

Chairman ROTH. One question.

Senator LEVIN. Would the hospitals and doctors be reimbursed if they had just performed the angioplasty?

ANONYMOUS INDUSTRY WITNESS. Yes.

Senator LEVIN. In other words, Medicare would be reimbursing them if they did not use the experimental device, but used the traditional device?

ANONYMOUS INDUSTRY WITNESS. Yes, they would be.

Senator LEVIN. Thank you, Mr. Chairman.

Chairman ROTH. As I stated earlier, prior to the exit of this witness, I direct that all cameras be turned to face either to the rear or to the window side of the hearing room, so I would direct you to do so now.

As far as individuals are concerned, everyone will please remain seated in the hearing room. Those of you who are standing to the rear can continue to stand there, but please do not move about as the witness leaves the room.

I will ask the Capitol Police whether all cameras have been redirected. I will now ask the Capitol Police to accompany the witness from the hearing room.

Our next witness is Jack Hartwig. Mr. Hartwig is the Deputy Inspector General of the Department of Health and Human Services. Mr. Hartwig, as you know, we swear in all witnesses who appear before this Subcommittee.

Mr. Hartwig, do you swear or affirm that the testimony that you will give before this Subcommittee will be the truth, the whole truth and nothing but the truth, so help you, God?

Mr. HARTWIG. I do.

Chairman ROTH. Please be seated and proceed with your testimony.

TESTIMONY OF JOHN E. HARTWIG, DEPUTY INSPECTOR GENERAL, HEALTH AND HUMAN SERVICES

Mr. HARTWIG. Good morning, Mr. Chairman and Members of the Subcommittee. I thank you for giving the Office of Inspector General the opportunity to testify on the subject of Medicare Investigational Device Coverage and the OIG's significant accomplishment in this area.

The Office of Inspector General plays the role of fact-finder for the department. As a fact-finder in our investigational device inquiries I believe we have accomplished four equally important objectives. First, we have identified a significant abuse by hospitals, device manufacturers and physicians of the Medicare program and

assisted the Health Care Financing Administration in identifying these inappropriate billing practices.

Second, we have identified an area of significant Medicare overpayments. Third, we have identified potential criminal violations relating to the submission of fraudulent Medicare claims and are making appropriate referrals of these cases to the Department of Justice. And, finally, we have served as a catalyst for a review of the Medicare coverage policy that the department believes will result in Medicare beneficiaries greater access to advances in technology.

In 1993, we were advised by the Health Care Financing Administration that it was concerned that several hospitals had billed Medicare improperly for millions of dollars worth of surgical procedures involving unapproved medical devices. Specifically, the Health Care Financing Administration alleged that these hospitals knowingly were billing Medicare for the implantation of pacemakers, defibrillators and other cardiac devices that had not been determined to be safe and effective by the Food and Drug Administration.

Under Medicare program rules then in effect, medical devices that had not been approved for marketing by the Food and Drug Administration were considered investigational and as such were not reimbursable by Medicare. In response to Health Care Financing Administration's allegations we opened an investigation to determine whether the hospitals practices violated any provisions of the various civil and criminal false claims statutes. In June of 1994, we issued 132 subpoenas to hospitals in 30 States for documents related to the billing of investigational cardiac devices.

The requests for documents drew strenuous objections from the hospitals and interested medical groups. The affected groups also turned to Congress for support, arguing that the Health Care Financing Administration's reimbursement policy unfairly deprived Medicare patients of the benefits of new technology.

Despite these challenges, we continued our investigation and eventually received several hundred boxes of responsive documents. These documents were logged and reviewed by teams of OIG special agents and auditors. As the investigations progressed the Department of Justice and Federal prosecutors were apprised of developments affecting the cases in their jurisdictions.

When discussing an investigation as complex as this one it is difficult to summarize its findings without over-simplifying the issues. However, several conclusions are readily apparent.

First, the majority of hospitals that we examined had billed for investigation cardiac device procedures that were not covered by Medicare and for which payment should not have been made.

Additionally, we found ample evidence that the majority of hospitals had some knowledge of the prohibition against billing Medicare for the implantation of an investigational device. We also identified close to 30 hospitals that appear to have knowingly submitted improper claims for procedures involving investigational devices and then took steps to obscure the experimental nature of the implanted devices.

We believe these hospitals intentionally defrauded the Medicare program. Furthermore, we believe that physicians knew that the

device they were about to implant in a patient was still awaiting FDA approval.

There are several ongoing activities to address these abuses. We are working with the Health Care Financing Administration to identify, calculate and recover over-payments made to the hospitals and physicians who improperly billed for these investigational devices. Where evidence of criminal conduct is uncovered we will certainly investigate.

With regards to evidence of fraud that has already been uncovered by us, we are making appropriate referrals to the Department of Justice for an assessment of the prosecutive merit of the case.

In addition to our criminal investigation involving the submission of improper claims relating to investigational devices, we also conducted a study in 1994, at the request of the Food and Drug Administration, to address concerns with the clinical testing of investigational devices. During our assessment of the testing process we found problems in the accounting and tracking of investigational devices and in hospital investigational device oversight, including the informed consent process.

We found that in the current environment investigational devices are often treated as if they were already approved as safe and effective. We are pleased to have been able to report to you on our contributions in this critical area. Our work in this area is not over. We will continue to work with the Health Care Financing Administration, the Food and Drug Administration and the Department of Justice to ensure that the integrity of the Medicare trust funds are preserved, our beneficiaries receive the highest quality of medical care and those who cheat the system are held accountable.

I thank you all for your support in this area, and I will be happy to answer any questions you may have. This is a summary of my official remarks which we had previously asked to be entered into the record.

Chairman ROTH. Your full statement will be included as if read.

What role does the Health and Human Services Inspector General play in investigating fraud in the Medicare program? Are you not the watchdog to prevent Medicare fraud?

Mr. HARTWIG. Yes, we are. We actually have, I think, three roles. Certainly the prevention of fraud, the detection of fraud and the investigation of fraud. The prevention of fraud, we certainly look to be involved in educational activities. Our office issues special fraud alerts. We do provide training and communications to the provider community.

The detection of fraud, the Office of Inspector General has an audit and an evaluation side which will proactively go out and review policies and procedures. We are looking certainly to improve those procedures in areas where abuse and fraud can occur. We also work closely with the Health Care Financing Administration and their contractors in their detection efforts. And certainly the Medicare contractors are probably the first line of defense in uncovering fraud.

Allegations come to our attention in a number of ways as in this case, from the Health Care Financing Administration and their contractors, from beneficiaries, from whistleblowers, Members of Congress and, where we are advised of allegations concerning cor-

rupt practices in the Medicare program, we certainly have criminal investigators who would investigate those allegations and, where appropriate, make referrals for prosecutive action.

Chairman ROTH. Has the Inspector General undertaken any investigation of the unethical physician practices described by the first witness?

Mr. HARTWIG. Yes, Mr. Chairman.

Chairman ROTH. Is that ongoing at this time?

Mr. HARTWIG. That is an ongoing investigation and our actual entry from the investigative side into the area of investigational devices was made in 1993. The Health Care Financing Administration and one of their contractors actually had concern about hospitals billing for investigational devices.

And we have, since that time, been looking into the billing practices of hospitals, obviously, throughout the country and that was the issuing of the 132 subpoenas. That inquiry is still ongoing today.

Chairman ROTH. And you have an ongoing inquiry on the unethical practices of the physicians as well?

Mr. HARTWIG. As it relates to their billing for investigational procedures, yes.

Chairman ROTH. What about the unethical medical practices; is that being investigated?

Mr. HARTWIG. It certainly is if it comes to our attention, yes. The question about unethical practice, I think we would have to proceed where we would have an ability. Certainly the Office of Inspector General has the exclusion on action. Some of the practices brought to the attention of our office also relate to the Food and Drug Administration. We have referred some of those particular allegations to the Food and Drug Administration as they legally fall under their purview and not ours.

It is certainly where we have uncovered unethical practices for which we could take action against, we would look to investigate those.

Chairman ROTH. Let me ask you this, are unwarranted, invasive procedures by doctors being investigated at the current time by the Inspector General?

Mr. HARTWIG. As part of our overall investigation of investigational devices, we have certainly looked at physicians and we would look where we would find evidence of physicians performing unnecessary services.

Chairman ROTH. Are you working on this matter with the first witness?

Mr. HARTWIG. Yes.

Chairman ROTH. The first witness also talked about the culture. Would you agree with the description given by the first witness as to the culture of the medical industry?

He did modify that to say it only involved 2 percent of physicians.

Mr. HARTWIG. I certainly think there is a percentage. It is difficult to give an actual percentage, but I believe there is certainly a percentage, 2 percent would be as good an estimate that I could come up with, where the culture is driven by greed. I think I would say that.

Chairman ROTH. Well, if I recall correctly, I think the first witness said that the industry did not enjoy a very high opinion of the effectiveness of the Inspector General. Why is that and what is being done to ensure that the watch-dog of the medical industry is seen as a tough bulldog.

Mr. HARTWIG. Yes. I certainly think within our resources we are a tough bulldog. I think you have to look at it as a philosophical question. You know, the health care industry and I think, Mr. Chairman, you said it in your opening remarks, is an industry where the foundation is trust. The basis of our health care program is a trust-based system. It is a system based on trusting the physicians, trusting all the providers, and it is a voluntary payment system. It is a system where providers, if they send in a bill, certainly in the Medicare program the system is designed to pay that.

I think the next issue you get to is deterrence, and how good is the Office of Inspector General in terms of deterrence? And that is just a question if the system is as corrupt as some people have estimated, you are never going to successfully investigate all those individuals. And what you really get down to is how well has the Office of Inspector General done in deterring criminal activity or abusive activity to occur?

I think we have done an excellent job, given the resources that we have. And, clearly, no agency has unlimited resources to do all those things. I believe that we have had a bigger impact on the industry than the witness. I personally think that we have had a bigger impact on the health care industry than the witness had testified to.

Chairman ROTH. You came up with a list of 132 hospitals in your current investigation which you subpoenaed for information. Did you find evidence of improper filing for reimbursement or even fraud?

Mr. HARTWIG. On our review of the 132 hospitals, yes.

Chairman ROTH. How many of the subpoenaed hospitals billed Medicare despite clear knowledge that it violated Health Care Financing Administration policy?

Mr. HARTWIG. I think our investigation disclosed about half of those hospitals billed Medicare for investigational procedures and knew that it was inappropriate to do so.

Chairman ROTH. What evidence did you find that some of those subpoenaed hospitals took steps to conceal that fact?

Mr. HARTWIG. There were a number of hospitals that we reviewed that took specific affirmative steps to conceal facts. This took a number of means. We found where some hospitals would split the bill for the investigational device, so if it were to cost $30,000 or $27,000, on their actual billing form, they would split it into three $9,000.

And we believe the reason for doing that is so not to have a very large item that might fall under the review for an auditor if an auditor looks at items to review. And we found a number of hospitals that would actually take one device on the billing side and split it into three devices or three codes.

We identified some hospitals that actually billed for a different procedure than was actually performed. Certainly we did find evidence of consent forms being removed from files and other docu-

mentation that was moved around for the reason, we believe, to disguise the true nature of their claimed submission.

Chairman ROTH. But would there be any other reason for removing the consent documents?

Mr. HARTWIG. There is a reason for removing the original consent document. I believe on some of the trials, the Food and Drug Administration requires the original consent document to be placed in a different file. I do not know that there would ever be a legitimate reason for moving copies of the consent documents. I would also point out that our assessment conducted by our Office of Evaluations and Inspections noted that the consent process, in itself, has had some problems that we uncovered as far as maintaining the forms in the first place, being able to find the forms, as far as the way the forms are written. And that was one of the items we had reported to the Food and Drug Administration.

Chairman ROTH. After you issued the subpoenas to the hospitals, how many interviews did you conduct?

Mr. HARTWIG. I am not familiar with the exact number. I will tell you that we started conducting interviews when the allegation first came to us. I just, I am sorry. I could find out, but I do not know the exact number of interviews that our agents would have conducted. I believe it is many.

Chairman ROTH. I understand there was a time when the Inspector General, for all practical purposes, shut down this investigation of clinical testing, is that correct?

Mr. HARTWIG. I do not——

Chairman ROTH. Why did that occur?

Mr. HARTWIG. I do not think that we shut it down. I will tell you that we made a decision and we had to make a decision as to the best allocation of the department's resources, and what was the next logical step to proceed in this investigation given the facts as we knew them and given the resources.

And at that time, we felt, given a number of reasons, that the best way to proceed was to use the Health Care Financing Administration intermediary auditors to go out, determine over-payments at the institutions and make collection efforts.

Chairman ROTH. When did that occur?

Mr. HARTWIG. I believe the first meeting would have been in September of this year.

Chairman ROTH. How long had you been aware of the problems with clinical testing?

Mr. HARTWIG. I think they came to our attention, I believe around June of 1993.

Chairman ROTH. And 2 years later, you took this step with the intermediary. Are they not the ones responsible for administering the reimbursement according to the policies of the Health Care Financing Administration?

Mr. HARTWIG. Yes.

Chairman ROTH. How many criminal investigations have resulted from the 132 subpoenas?

Mr. HARTWIG. We are currently involved in one ongoing criminal investigation.

Chairman ROTH. Only one?

Mr. HARTWIG. Only one currently.

Chairman ROTH. Are any others being looked into or is that the total number?

Mr. HARTWIG. I believe our investigations are certainly ongoing and——

Chairman ROTH. You said, "You believe;" are they or are they not ongoing?

Mr. HARTWIG. They are ongoing.

Chairman ROTH. Since the intermediaries, who are the Medicare auditors, serve as the Health Care Financing Administration's first-line of defense against fraud and abuse, should they have detected the extent of the problem and acted upon it sooner?

Mr. HARTWIG. I will answer the question, yes. I will say, however, that the initial allegation came from an intermediary. But certainly the intermediaries would be the individuals that would act——

Chairman ROTH. When was that?

Mr. HARTWIG. That was in 1993.

Chairman ROTH. That was in 1993, but 2 years later we still have a serious problem in this same area.

When you kicked off what you called Project Jump Start, there was great acclaim in the press for the Inspector General's aggressiveness in pursuing Medicare fraud. Yet, nearly 2 years later, you have only one open criminal case and not one dollar in recoupment.

It does not appear to me that you are living up to your own press findings. What is your comment? Why have you not been able to effectively do something about this?

Mr. HARTWIG. Well, I would really argue that, well, not argue, but I would just state that as you look at the entire role of the Office of Inspector General, certainly there have been policy changes by two agencies, the Food and Drug Administration and the Health Care Financing Administration. The investigation, I will admit, has been a very time-consuming investigation but it is a very complex investigation involving a number of institutions and it took time. Our attorneys took time getting compliance from 130 hospitals. The review of those documents took time and took a lot of effort on our part.

We have actually invested, as an organization, over 4,000 hours. I believe our first civil settlement was probably signed yesterday and that was a little over $1 million, and certainly we see some very significant over-payment recoveries in this area.

Chairman ROTH. Are they currently being processed?

Mr. HARTWIG. Yes. The next step and that is actually what we are trying to do now is determine specific over-payments at specific institutions and then make decisions after each of those over-payments are uncovered as to the best way to proceed at that time. Certainly if allegations, based on that review, are of a criminal nature we would certainly investigate those.

Chairman ROTH. Senator Dorgan?

Senator DORGAN. Mr. Hartwig, you heard the testimony this morning by the witness who characterized the attitude of some providers and doctors. From the earlier testimony, one would conclude that these people view the Federal Government as a Paper Tiger. They seem to think they can cheat, they are not going to get

caught, and the government is not going to find evidence of the cheating

Why would doctors in cardiac suites feel that way?

Mr. HARTWIG. I think it gets down to their opinion as to whether or not they will actually get caught. And I am sure that their view is that they do this for years, that they have never been caught and they never will be caught. I cannot defend that attitude.

I will tell you that we try to do our best to prioritize our investigations where we can have the greatest impact, both criminal, civil and administrative. And it is a challenge to us to make those priorities where we are going to have the greatest return.

Senator DORGAN. When you describe—I do not know much about what you all do down in your office—but when you describe the investigation at 4,000 hours, you are talking about two people working 1 year.

Mr. HARTWIG. Yes.

Senator DORGAN. That seems to me not much of an allocation of resources to try to respond to and deal with the kinds of allegation of fraud that we heard described here.

Mr. HARTWIG. That was certainly, looking to this case, we certainly have other investigations ongoing. We really looked to do this investigation in a number of steps. As we started, we—certainly as you look at the complexity of this issue—wanted to focus on some of the more egregious areas; there is a learning curve here, to look at a few institutions areas early on. Those hours were expended by not only agents, criminal investigators, but certainly auditors and attorneys for our office.

And, again, there was the issue of compliance. There is the issue of the amount of detail and complexity of this.

Senator DORGAN. Well, try to give me some notion of how much effort is involved in investigations. I read in a newspaper article here, a while back, that there were 100 FBI agents in Arkansas investigating Whitewater with the Special Counsel, I believe.

So you have, on that issue, 100 FBI agents in the State of Arkansas investigating. I do not know how long they were there.

But on this issue of Medicare fraud, as we describe it in this hearing, what kind of resources exist out there for investigative purposes?

Mr. HARTWIG. Certainly in our office we have 175 criminal investigators for the entire country. The Federal Bureau of Investigation has committed resources, the Postal Inspection Service has committed resources. I can tell you, from a personal point of view, our resources have actually been going down over the last few years.

Senator DORGAN. So describe that for us, would you? The investigative resources are diminishing?

Mr. HARTWIG. Our investigative resources are diminishing, our audit resources have diminished and our evaluation resource have diminished and certainly, Senator, and you had mentioned it earlier, under the continuing resolution our ability to travel and our ability to actually incur investigative expenses or audit expenses have been greatly diminished.

When you asked about the question of a criminal investigation, you know, the burden of proof is beyond a reasonable doubt and it is a rather substantial burden and where a lot of these crimes

can occur on a wholesale basis. What you are looking here is a wholesale activity—and our investigation disclosed it—it is done in numerous hospitals throughout the country, not just with cardiac devices, but we believe with all investigational devices. To attack that problem from a criminal investigative point of view, you then attack that wholesale problem on a retail basis, a claim-by-claim, proving that a particular claim is false, proving that that claim was knowingly submitted.

Senator DORGAN. I understand.

Mr. HARTWIG. It is not uncommon for our investigations to take 4 or 5 years from start to finish.

Senator DORGAN. Well, would you submit for the record for this Subcommittee the diminished resources year-by-year, with respect to investigations and also submit for us the diminished resources with respect to the continuing resolutions.

Let me ask you another question——

Chairman ROTH. I think that is an important point, but I do think it should be noted that, between fiscal year 1987 and fiscal year 1995, there have been 3 years in which the OIG has received more money than they have requested—fiscal years 1987, 1990, and 1994.

So I just think the record ought to reflect that.

Senator DORGAN. And I do not know what they requested. But we have had this issue on the floor of the Senate with an amendment by a colleague of mine very recently. I would observe that right now we are talking about spending cuts to diminish the resources available for investigating fraud. And I think it is important to include that at a hearing when we are talking about the evidence of fraud.

I would also make a point that the reconciliation bill that the President vetoed recently included a provision—I think that came from the House side, not the Senate side—but a provision dealing with the Medicare and Medicaid civil monetary penalty. The bill would have changed the standards to make it more difficult to prove fraud. Current law required that providers use reasonable diligence in submitting claims, to make sure the claims are true and accurate. The reconciliation bill would have made providers liable only if they act with deliberate ignorance or deliberate disregard of false claims. The bill would have lowered the standard and made it easier actually for those who would file fraudulent Medicare and Medicaid claims. Under the bill, fewer providers would be liable for civil and monetary penalties for fraud.

Chairman ROTH. I would point out to my distinguished colleague that there was such a proposal, I think, on the House side. At the Senate insistence, that was taken out.

Senator DORGAN. You are right, it did come to the conference committee from the House side. However, my understanding is that it was included in the conference report, as Section 8132 of the final bill.

But my point is that we need to toughen up in these areas. We need adequate resources to investigate, and we need adequate standards to allow us to bring to account and bring to justice those folks who defraud the government.

I would like to ask one additional question. You indicate you have 175 criminal investigators. Five years is too long to make cases. I think everybody would say we understand the difficulty, but 5 years is too long. How many criminal cases have you brought to a conclusion? How many criminal——

Mr. HARTWIG. I think, we actually—and I say 5 years is certainly not the average. Some of these cases can take up to that and that involves the initial allegation phase, it involves the investigative phase, and it involves the prosecutive stage. And in some instances it would involve, certainly, the trial phase. And that is why I say, from beginning to end.

We are certainly looking, and I think as you get into some of the coordinated efforts that law enforcement is now getting into in the health care area, we are certainly looking to reduce the amount of time it will take to prosecute because we realize that the quicker you can bring these cases to fruition, you know, if you can reduce the amount of time then you automatically increase resources.

And clearly for Federal executives, living within whatever your budget is and getting the most out of what you have is a tremendous challenge.

Senator DORGAN. How many criminal cases have you prosecuted, have you filed?

Mr. HARTWIG. We actually, we generally in a given year bring about approximately 200 criminal convictions. In our office we also handle program exclusions. And we exclude about 1,000 providers for a number of reasons, either because they've been convicted of a crime or some of the other permissive exclusions.

One of the things that I always bring about and if you will allow I do have some propaganda that I always carry with me. It just talks about, when you talk about the deterrence, I will say that we have last year, based on audits, investigations, and evaluations, the department implemented about $10 billion in savings.

Now, we actually return about $9 million for every employee we have and that has almost doubled in the last 4 years. But, clearly you always look to get the most you can out of what you have. And I understand that the industry may feel that we are a Paper Tiger.

Senator DORGAN. And that is a problem.

Chairman ROTH. I am going to have to ask if we can move ahead.

Senator DORGAN. Let me just conclude by saying that if that is what the industry feels, that you are a Paper Tiger, that is a serious problem. That perception has to change and it has to change with more resources, more aggressive prosecution and the determination that fraud, where it is found, is going to be prosecuted vigorously and aggressively.

Mr. HARTWIG. And aggressively and I think that even targeting is another area; looking to target specific instances, either in the home care industry or the hospital industry and look to really try to have a deterrent impact with what you do.

Chairman ROTH. Senator Levin?

Senator LEVIN. Thank you, Mr. Chairman.

Of the hospitals that you have subpoenaed, you indicated that 50 percent, you believe, knowingly submitted claims for procedures that were using investigational devices and, therefore, were not reimbursable. In the other 50 percent were they not reimbursable but

they did not submit them knowingly, or how would you describe the other 50 percent?

Mr. HARTWIG. I would describe the other 50 percent as we did not have evidence that they knew. We believe most of the hospitals submitted claims for investigational devices. In half of those instances we were able to, through our investigation, determine that half of them actually knew that those devices were non-reimbursable.

The other half we have not been able to determine, we do not know as of yet whether they knew or they did not know.

Senator LEVIN. So it is not as though you have determined that in half the cases you cannot prove knowledge, it is that you have only addressed half the cases, and in all those cases you believe they knowingly submitted nonreimbursable claims?

Mr. HARTWIG. In all those cases we believe that they submitted claims for investigational devices to the Medicare program which should not be reimbursed. In about half we were able to show that they knew that they should not have submitted those claims. And then there was another percentage that actually took affirmative steps to in some way disguise that claim for reimbursement.

Senator LEVIN. And did you find that in some cases they submitted claims that could not be reimbursed but that you could not show were submitted knowingly?

Mr. HARTWIG. Yes, clearly.

Senator LEVIN. How can you submit a claim for an experimental device and not know that it is not reimbursable?

Mr. HARTWIG. It gets to proving the knowledge of hospital officials as to a particular regulation and I am not saying that they did or did not know. I am clearly pointing out that we were able to determine that they did know. What you really look for is documentation submitted by the hospital and clearly that is what we looked at.

Senator LEVIN. Is there some uncertainty, or was there some gray area as to what is reimbursable or not or was it clear?

Mr. HARTWIG. I think that the Medicare policy, as written in the carrier manual, was clear that the Medicare program does not pay for investigational devices.

Senator LEVIN. Was there some gray area in terms of the implementation or the interpretation of the policy?

Mr. HARTWIG. Certainly there are two sides to every story and there were, we did hear, during the course of our investigation, some of those issues being raised.

Senator LEVIN. Have the rules been changed subsequently so that some things which previously were not reimbursed are now reimbursable?

Mr. HARTWIG. In September of this year, the HCFA and the Food and Drug Administration announced changes to their, in the Medicare sense, HCFA announced a change to their reimbursement policy and the Food and Drug Administration announced some changes to their classification of investigational devices.

That policy took effect in November of this year, and that will prospectively allow the Medicare program to start reimbursement for investigational devices.

Senator LEVIN. Were some of the devices that you found were not reimbursable at the time that the claim was made, would they now be reimbursable?

Mr. HARTWIG. Yes. Many of the claims that we would look at that were not reimbursable in 1994, would currently, that same claim would be reimbursable under the current policy today.

Senator LEVIN. You know, that seems to me to be one important area and if something is not reimbursable there should not be a claim filed for it. I think that is what you are after. That the rules have changed and some of those items are now reimbursable. That is one whole area that is important that it be, that work be done on it, that we recoup any money that was paid out that should not have been paid out.But there is another whole area that seems to me is now kind of overwhelming this question as to whether we ought to be reimbursing for experimental procedures and that is the question of this double procedure that was being used, according to this witness. And he said in dozens of cases and in dozens of places that he witnessed—which presumably means that since he is only one person, that you multiply that by I do not know what factor, and you come up with hundreds or thousands of places—I presume, if we assume that this witness is accurate in his statement where not just an experimental was used which was not reimbursable—properly used by the way, right, FDA approved and all the rest and the hospital approved it, is that correct—these devices were used with the approval of the FDA as experimental devices, is that correct?

Mr. HARTWIG. Yes.

Senator LEVIN. And the hospital committee, the independent review board of the hospitals approved the use of the devices?

Mr. HARTWIG. Yes.

Senator LEVIN. So, the issue is whether or not then they were properly reimbursable. That is one whole issue. And that is an important issue and there have been some changes made in the reimbursement.

The other issue that is raised here, it seems to me, is even more significant, which is the criminal assault of dozens of patients, a double procedure being used, an invasive procedure being used after the one that was supposed to be used was used. What he says is he witnessed dozens of times in dozens of different places invasive procedures, invading the body of patients in order to establish proof so that a Medicare examiner would then see a picture of a balloon.

Now, that is a whole new kettle of fish, and as far as I am concerned a very important kettle of fish, as important as the reimbursement issue is and whether or not reimbursement was properly made. The tort, the probably criminal tort that was described by this witness on dozens of people in dozens of places, it seems to me is also important to investigate.

Now, I would ask you this, I gather that you have seen some evidence, at least in one place, of something like that happening. When you see, if you did see evidence of something like that happening would that be, then, forwarded to a criminal prosecutor?

Mr. HARTWIG. We are certainly forwarding cases of criminal nature to the Department of Justice and we are certainly working

with the Department of Justice. Some of the allegations actually have fallen under the purview of the Food and Drug Administration and we have forwarded those allegations to the Food and Drug Administration for their investigative side to work.

Certainly the question that has also arisen is where we uncover a poor or abusive quality of care, the Medicare program has peer review organizations to review that care and to recommend sanctions against the individuals and certainly we will look into those instances for that type of sanction.

Senator LEVIN. Would you agree that the allegations here would, if true, result in serious ethical misconduct?

Mr. HARTWIG. Certainly ethical misconduct. I might also point out in our evaluation that I had also proceeded to brought out in a number of these investigational devices, as you raised, not just from the billing side, but from the oversight of the investigational device testing, you know, a somewhat of a breakdown in that system as well. That we have kind of focused on the Medicare billings and, again, the Office of Inspector General has expanded somewhat to look at Food and Drug Administration oversight into the investigational device process.

Senator LEVIN. Have you gone through with this witness the dozens of places that he alleges he saw dozens of different doctors unethically implant devices that were not needed medically solely for the purpose, he claims, of providing evidence for a subsequent reimbursement for Medicare, have you gone through the dozens of places and dozens of doctors with him?

Mr. HARTWIG. We have interviewed him—I certainly have not—but our agent has interviewed him on a number of occasions concerning that particular allegation.

Senator LEVIN. Have you gone through names and places and dates with him?

Mr. HARTWIG. Names and hospitals. I do not know that he has given us particular dates.

Senator LEVIN. Well, I think it is pretty serious stuff and you ought to find dates, names, places and get that, if it is true, get that information to the proper authorities, because that is a double ethical violation. That is a reimbursement issue but that is also a tort. You cannot do that. You cannot perform a procedure on a patient that is not medically indicated in order to provide evidence for mere reimbursement.

You know, the story may or may not be accurate, so I am not in any way prejudging its accuracy. All I am saying is that I would hope that you would promptly have your people go through and get those names and places that he alleges and if you think there is any accuracy to it, provide that information to the proper authorities. Will he do that?

Chairman ROTH. If I could, we are going to have to move on.

Senator LEVIN. Well, I just want to get an answer.

Mr. HARTWIG. Yes, sir.

Senator LEVIN. And I have one last question. Who, in your office, encouraged this witness to file a lawsuit under the Federal False Claims Act?

Mr. HARTWIG. I do not believe anyone in our office encouraged him.

Senator LEVIN. Well, he said someone in your office.

Mr. HARTWIG. I know he said that. I do not know of anyone in our office that encouraged him. I will tell you that someone in our office did supply him with a copy of the False Claims Act. But I do not believe anyone in our office encouraged him.

Senator LEVIN. That was the word he used.

Thank you, Mr. Chairman.

Chairman ROTH. The hour is growing late and we have a long list of witnesses to hear from today. Our first witness did make a number of serious charges. They warrant investigation. Of course, they are, at this stage, just the charges of one individual but I would hope that for the remainder of this morning we could direct our attention to the immediate problem so that we can complete the hearing at a reasonable hour.

I would point out to you, Mr. Hartwig, that the attorneys representing one of our upcoming witnesses, the University of Washington Medical Center, have requested that certain questions be submitted to you. My intent is to submit these questions in writing to you and have you answer them for the record where they will be made available to the public and to those requesting the inquiries.[1]

Thank you, Mr. Hartwig.

Mr. HARTWIG. Thank you.

[The prepared statement of Mr. Hartwig follows:]

PREPARED STATEMENT OF JOHN E. HARTWIG

Good morning Mr. Chairman and Members of the Committee. I am John E. Hartwig, Deputy Inspector General for Investigations, Office of Inspector General of the United States Department of Health and Human Services and I thank you for giving us the opportunity to testify on the subject of Medicare coverage of investigational devices and the OIG's significant accomplishments in this effort.

Overview—The Office of Inspector General

By way of background, the Office of Inspector General (OIG) was created in 1976, and is statutorily charged with protecting the integrity of departmental programs, as well as promoting their economy, efficiency, and effectiveness. The OIG meets this statutory mandate through a comprehensive program of audits, program evaluations, and investigations designed to improve the management of the Department and to protect its programs and beneficiaries from fraud and abuse.

Our role is to detect and prevent fraud and abuse, and to ensure that beneficiaries receive high quality, necessary services, at appropriate payment levels. We have been extensively involved in examining the Department of Health and Human Services' policies concerning investigational medical devices. I will first report on our investigation of improper billing by hospitals for procedures involving devices not approved by the Food and Drug Administration (FDA) for general marketing. I will then describe our assessment of whether controls over clinical testing of investigational devices adequately ensure patient safety and sound clinical research.

The Investigation of Hospital Billings for Investigational Devices

In 1993, the OIG was advised by the Health Care Financing Administration (HCFA) that it was concerned that several hospitals had billed Medicare improperly for millions of dollars worth of surgical procedures involving unapproved medical devices. Specifically, it was alleged that these hospitals knowingly were billing Medicare for the implantation of pacemakers, defibrillators and other cardiac devices that had not been determined to be safe and effective by the FDA. Under Medicare program rules then in effect, medical devices that have not been approved for marketing by the FDA were considered investigational, and as such were not reimbursable by Medicare. The policy prohibiting payment for these experimental devices

[1] The documents referred to were marked Exhibits 27 and 29, and are retained in the files of the Subcommittee.

had been clearly set out in the Medicare Hospital manual provided to all hospitals participating in the Medicare program.

In response to HCFA's request, the OIG opened an investigation to determine whether the hospitals' practices violated any provisions of the various civil and criminal false claims statutes. OIG subpoenas were issued to five manufacturers of the investigational devices in October 1993.

In March 1994, the investigation significantly expanded to determine whether the deliberate use of improper billing codes was part of an industry-wide abuse that encompassed both hospitals and many medical device manufacturers. In June 1994, the OIG issued over 130 additional subpoenas to hospitals in 30 States for documents related to the billing of investigational cardiac devices.

The requests for documents drew strenuous objections from the hospitals and interested medical groups. Our attorneys then engaged in protracted negotiations with lawyers for some of the subpoenaed hospitals before the requested materials were produced. The affected groups also turned to Congress for support, arguing that HCFA's reimbursement policy unfairly deprived Medicare patients of the benefit of new technologies. The industry's request for legislative relief produced proposed legislation that not only would extend Medicare coverage to procedures involving new devices, but also make the revised rules retroactive, thus possibly nullifying the basis of the OIG investigation.

Despite these challenges, OIG continued its investigation and eventually received several hundred boxes of responsive documents. These documents were logged and reviewed by teams of OIG Special Agents and auditors. As the investigations progressed into early 1995, the Department of Justice and Federal prosecutors were apprised of developments affecting the cases in their jurisdictions.

Findings of The OIG Investigation

To date, we have invested over 4,000 staff hours to analyzing documents, developing leads and conducting interviews in furtherance of the investigational devices investigation. When discussing an investigation as complex as this one, it is difficult to summarize its findings without oversimplifying the issues. However, several conclusions are readily apparent.

First, the majority of hospitals that we examined had billed for investigational cardiac device procedures that were not covered by Medicare and for which payment should not have been made. The number of improper billings on a per-hospital basis ranged from less than 10 to in excess of 400 procedures. Although additional audit work must be completed before we know the precise amount of the improper payments, it is clear that Medicare was misled into paying millions of dollars to hospitals for procedures using these experimental devices.

Based upon our evaluation of the documents provided in response to the OIG subpoenas, the level of culpability of the hospitals also varied. We found ample evidence that the majority of hospitals had some knowledge of the prohibition against billing Medicare for the implantation of an investigational device.

We also identified close to 30 hospitals that appear to have knowingly submitted improper claims for procedures involving investigational devices and which took steps to obscure the experimental nature of the implanted device. We believe these hospitals intentionally defrauded the Medicare program. In addition, we have questions concerning the role played by the physicians in the implantation of investigational devices, as they may bear some responsibility for these fraudulent claims. After all, as clinical investigator for the medical device manufacturer, the physician must submit research protocols to the hospital's institutional review board (IRB) prior to the use of the investigational device in clinical trials. Furthermore, we believe physicians must have known that the device he or she was about to implant in a patient was still awaiting FDA approval.

In view of these findings, Inspector General June Gibbs Brown has written to Bruce Vladeck, the Administrator of HCFA, urging that HCFA recover the overpayments made to the hospitals and physicians who improperly billed for these investigational devices. She fully supports the recovery of these funds and has directed my staff to work closely with HCFA to facilitate the recovery effort. She also requests that HCFA take steps to ensure that the hospitals do not attempt to offset the repayments to Medicare by billing the patients who received these devices. In any case where the audits to determine the amount of overpayments uncover evidence of criminal conduct, the matter will be referred to OIG investigators for further investigation.

Although the recovery of overpayments is a priority, let me state again that the OIG also supports the prosecution of entities and individuals engaged in criminal fraud. With regards to the evidence of fraud that already has been uncovered by

the OIG, we will make appropriate referrals to the Department of Justice for an assessment of the prosecutive merit of these cases.

Assessment of Controls Over Clinical Testing of Investigational Devices

In addition to investigating the submission of improper claims related to investigational devices, we conducted a study in 1994 at the request of FDA to address concerns with the clinical testing of investigational devices. FDA was particularly concerned about manufacturers distributing investigational devices outside of clinical trials and clinical investigators implanting devices in patients who do not fit clinical protocols. The design and size of clinical trials are carefully determined to minimize the number of patients exposed to risk while still generating information to establish efficacy of the device.

We traced four investigational devices through the clinical trials process from the manufacturer to the clinical investigator and local hospital where clinical research is carried out. All of these devices in our review were significant-risk, implantable devices, but were not part of our investigation on hospital billing practices.

During our assessment of the testing process, we found problems in the accounting and tracking of investigational devices and in the local oversight by IRBs, including the informed consent process. With three of the devices we found problems with the distribution outside of the approved clinical trials. One device was distributed in excess of the approved protocol, with one clinical investigator clearly implanting devices in more patients than the local review board or FDA had granted permission. Two of the devices we focused on were not properly accounted for among clinical investigators.

The study also identified potential weaknesses in local oversight of clinical trials. We found that institutional review boards within hospitals have difficulty monitoring clinical trials. They are dependent on information provided by clinical investigators and may not independently verify data. We found several cases where clinical investigators violated orders from the local review board or began implanting devices prior to approval. Also, we found problems with the informed consent process, including incomplete or missing informed consent documents. In some cases, patients may have been unaware that they had received investigational devices.

We found that in the current environment, investigational devices are often treated as if they were already approved as safe and effective. Although regulations clearly require careful accounting and limit use to approved clinical trials, our examples illustrate precisely how limits may be exceeded. While our limited case studies do not indicate how widespread these occurrences are, our findings raise concerns about the process for clinical testing for major investigational devices. The FDA is working on a number of improvements to improve compliance with appropriate regulations. Since our work was completed, FDA has revised guidance documents to sponsors, clinical investigators, and institutional review boards to clarify responsibilities and ensure compliance.

With your permission, Mr. Chairman, I would like to submit a copy of the assessment report, entitled "Investigational Devices: Four Case Studies" for the record. We are pleased to report that the FDA is working on both specific concerns raised in our report and general improvements to ensure that clinical trials for investigational devices are conducted with high ethical standards and in compliance with all Federal rules.

Conclusion

We are pleased to have been able to report to you on our contributions in this critical area. The Office of Inspector General plays the role of the fact finder for the Department as well as providing an accurate assessment of the Department's policies. I believe that through our efforts to date we have accomplished four equally important objectives. First, we have identified a significant abuse by hospitals and physicians of the Medicare program, and assisted HCFA in identifying these inappropriate billing practices. Second, we have identified a source of significant Medicare overpayments and will support the ongoing overpayment collection efforts. Third, we have identified potential criminal violations relating to the submission of fraudulent claims and are making appropriate referrals of these cases to the Department of Justice. Finally, we have served as the catalyst for a review of a Medicare coverage policy that has resulted in a change that the Department believes will allow Medicare beneficiaries greater access to advances in technology.

Our work in this area is not over. We will continue to work with HCFA, FDA and the Department of Justice to ensure that the integrity of the Medicare Trusts Funds are preserved, our beneficiaries received the highest quality of medical care and those who attempt to cheat the system are held accountable. We thank you for your support of our efforts and I will be happy to answer any questions you may have.

Chairman ROTH. Our next witness is Thomas Ault who is the Director of the Bureau of Policy Development of the Health Care Financing Administration of the Department of Health and Human Services.

Mr. Ault, as you know, we swear all witnesses.

Do you swear or affirm that the testimony that you are about to give to the Subcommittee is the truth, the whole truth and nothing but the truth, so help you, God?

Mr. AULT. I do.

Mr. KAVANAUGH. I do.

Chairman ROTH. Please be seated, and would you introduce the individual accompanying you and then proceed with your statement.

TESTIMONY OF THOMAS AULT, DIRECTOR OF THE BUREAU OF POLICY DEVELOPMENT, HEALTH CARE FINANCING ADMINISTRATION; ACCOMPANIED BY GARY KAVANAUGH

Mr. AULT. Yes, good morning, Mr. Chairman, and Members of the Subcommittee. I am Thomas Ault, Director of the Bureau of Policy Development in the Health Care Financing Administration. And I am accompanied by Gary Kavanaugh, on my right, who is the Deputy Director of our Bureau of Program Operations.

Chairman ROTH. I would ask you, if you can, to summarize in part your statement, but in any event, your full statement will be included as if read.

Mr. AULT. We are pleased to be here today to discuss the issue of Medicare coverage of investigational medical devices and services associated with those devices. As you know, there has been considerable interest in this topic over the past year. The law specifically provides that Medicare shall make payment only for items and services that are reasonable and necessary for the treatment of illness or injury.

Historically the interpretation of the terms "reasonable and necessary" by the Health Care Financing Administration has required that services must be safe and effective and not experimental. In the case of medical devices, since the 1970's, Medicare has looked to the Food and Drug Administration, FDA. Devices approved by the FDA were considered safe and effective and not experimental by Medicare. On the other hand, the fact that a device was being used in clinical trials pursuant to an investigational device exemption (IDE) from the FDA was seen by Medicare as an indication that the device was experimental, and these devices were not covered under the Medicare program until they received final approval from the FDA.

This policy was not established so that Medicare could avoid paying claims, but to protect beneficiaries from services that had not been found to be safe and effective. Medicare's policy of not covering investigational and experimental devices is longstanding and, in fact, stems from the inception of the program.

A letter to the fiscal intermediaries in January of 1977 clearly explained the policy. It stated the following, and I quote: "Since the beginning of the Medicare program, the Bureau of Health Insurance has tried to emphasize to physicians and beneficiaries that our decision to deny payment for a particular medical item or serv-

ice because it is considered experimental or investigational is not a judgment that a physician's choice of treatment is inappropriate, or that a patient does not need treatment. These decisions are, first, required of us by the law, Section 1862(a)(1), and are based on qualified medical advice that the items and services have not been generally accepted by the professional medical community as effective and proven treatments."

Medicare's program instructions on medical devices, which were governing until November 1, 1995, were added to the Medicare Hospital Manual, the Carrier Manual, and the Intermediary Manual in 1986. These instructions stated clearly: "Medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary."

This is quoted from the Medicare Hospital Manual. The instructions went on to explain that payment would not be made either for the devices or the procedures and services performed using the devices.

I would like to emphasize that HCFA was clear from the start about its policy regarding both coverage of investigational devices, as well as any related services.

To provide an example of how the policy was designed to work, if a hospital admission was solely for the purpose of implanting an investigational device, no payment would be made for the hospital stay. On the other hand, if a patient was admitted for chest pain, but it was decided during the visit to implant an investigational device, Medicare would pay for a medical admission, recognizing the chest pain. However, Medicare would not pay the much higher rate applicable to a surgical stay. No payment would be made for services associated with the surgical procedure to implant the investigational device.

This payment policy was designed to protect beneficiaries against the use of devices that the FDA had not found to be safe and effective, and devices that had not yet been generally accepted by the medical community. Not all of the devices that are available on a limited basis in a clinical trial are ultimately approved. Problems are sometimes discovered in the course of the clinical trial, and some devices fail to ever receive final FDA approval.

As you are aware, HCFA carefully revaluated its coverage policy for investigational devices last year. We considered the rapid rate of technological change and improvements made to medical devices that exist today and examined, with the FDA, the plausibility of creating a mechanism to distinguish among differing types of devices that were under an IDE.

As a result, HCFA issued a final rule in September of 1995 that would allow for expanded Medicare coverage of investigational devices. This rule was effective for services performed on or after November 1, 1995.

HCFA and FDA entered into an interagency agreement to establish a process for placing devices that were investigational into one of two categories based on level of risk. The first category, or Category "A," is for novel, first-of-a-kind devices, for which absolute risk of the device type has not yet been established.

The second category, or Category "B," is for devices for which the underlying questions of safety and effectiveness have been resolved for that type of device. These devices are often newer generations of already proven technologies.

Under the new policy, Medicare may now pay and cover items and services associated with the use of Category "B" devices within the context of the FDA approved clinical trial, as long as the device meets other Medicare coverage criteria.

Given the fact that a mechanism could be created to distinguish between the level of risk, HCFA determined that some, but not all, devices could be covered without compromising patient safety, and that these devices should be made available to Medicare beneficiaries who wanted to participate with their consent in clinical trials.

I would like to emphasize that this change is a new policy. It is not retroactive and has no bearing on past billing practices. We continue to believe that the prior policy, which was designed to protect beneficiaries against devices that the FDA had not found to be safe and effective, was the best approach available at the time.

I would now like to address the issue of inappropriate payments made to hospitals for investigational devices furnished prior to last year's final rule. Please note that there is ongoing litigation between the Department and 25 hospitals related to the hospitals' claim that the Secretary failed to comply with requirements of the Administrative Procedures Act in issuing policy in this area. I cannot comment on issues related to this litigation.

As you just heard, the Office of Inspector General has uncovered cases where erroneous payments were made for items and services related to the implantation of investigational devices. In response to the OIG investigation, hospitals have made various statements about our policy and the cause of the overpayments.

Some hospitals have stated that HCFA's policy was unclear, and others have stated that they did not know about it. As I said before, however, the policy was plainly contained in Medicare's manual instructions, including the Hospital Provider Manual. That manual explains and interprets the statute and the rules on coverage, payment, and billing that govern operation of the program, and hospitals know that these rules are binding.

If hospitals felt that the policy was unclear, we believe they should have made attempts to discuss it with HCFA. On any issue of uncertainty providers are encouraged to seek clarification from us. Conversely, if the policy is clear but providers disagree with it, the proper course of action is the same—to contact HCFA. We are always willing to investigate and reevaluate a policy issue brought to our attention by concerned parties.

The Medicare system is highly complex and deals with a large volume of individual claims. HCFA tries to ensure that its policies are being implemented correctly through focused payment safeguard efforts, such as prepayment review, postpayment review, and audits. And, as I will discuss in a few minutes, we support other payment integrity ideas that would require legislation.

We are disturbed that improper payments were unknowingly made by Medicare for investigational devices and that these improper payments went undetected for so long. However, we are also

disturbed that providers continued to bill us despite the fact that it was clearly contrary to our written policy. Avoiding improper payments in the Medicare program depends heavily on the integrity of providers to bill us responsibly and honestly.

The situation Medicare faces is similar to that of the Internal Revenue Service in administering the tax system. We expect providers to adhere to the rules stipulated in the manuals and to contact us if they do not understand them or if they are unsure of their responsibilities.

Finally, I want to make clear that hospitals were not confronted with the dilemma of having to bill illegally in order to receive payment for providing patient care services. We believe that in almost every instance in which an investigational device was provided, hospitals could have furnished an approved device, legally billed for it, and received payment. The choice they made, however, was to bill improperly for devices that were part of a clinical trial and, therefore, not covered.

If Medicare paid claims that were billed inappropriately—in this case for medical devices that had not been approved by the FDA—those payments constitute overpayments that are subject to recovery by HCFA. We are already at work identifying overpayments, and we expect to seek recoveries in accordance with the Debt Collection Act and the Medicare Act. This effort will help to ensure the integrity of the program.

I would like to point out, however, that we may be limited in our overpayment recovery efforts by the level of resources available. Current funding to pursue payment safeguard activities is inadequate because the continuing resolution provides resources at last year's level, despite the continuing increase in the volume of Medicare claims.

There appears to be growing support in Congress for the need to invest in payment safeguards and we hope that funds will be appropriated at a level commensurate——

Chairman ROTH. Mr. Ault, let me make a comment there, because while I do not disagree that you may need more resources, I would just point out, again, that in several years including 1994, in which this was an important matter, you got more funds than were requested. So I do not think the lack of action can be put entirely on the basis of lack of funds. And I just think the record should show that. Please proceed.

Mr. AULT. Thank you, Senator. I would like to close by commenting on various legislative proposals to strengthen our payment safeguard efforts, including overpayment recovery. While Medicare's payment integrity activities are improving, they need further improvement, and we look forward to working together on this subject with this Subcommittee and others in Congress. To ensure the effectiveness of our payment integrity activities, they need stable and reliable funding. The President and the Congress have addressed this need by including in various balanced budget plans a provision that would provide stable funding for payment integrity activities.

We urge you and your colleagues to retain such a provision in any further Medicare legislation. I am happy to be here today to discuss this important issue. I want to stress again that we should

not take lightly the fact that hospitals were consistently billing Medicare and receiving overpayments for care and services related to investigational devices.

We hope that situations such as this can be avoided in the future through both our reliance on the integrity of providers and the strengthening of our payment safeguard efforts.

Thank you, and I will be happy to answer any questions you may have.

[The prepared statement of Mr. Ault follows:]

PREPARED STATEMENT OF THOMAS AULT

I am pleased to be here today to discuss the issue of Medicare coverage of investigational medical devices and services associated with those devices. As you know, there has been considerable interest in this topic in the last year. I would like to begin by explaining Medicare's coverage policy as it existed prior to November 1, 1995.

Policy Prior to November 1995

The law specifically provides that Medicare shall make payment only for items and services that are reasonable and necessary for the treatment of illness or injury. Historically, the interpretation of the terms "reasonable and necessary" by HCFA has required that services must be safe and effective and not experimental. In the case of devices, Medicare has looked to the Food and Drug Administration (FDA) since the 1970's when Congress charged it with responsibility for assuring the safety and effectiveness of devices. Devices approved by the FDA were considered safe and effective and not experimental by Medicare. On the other hand, the fact that a device was being used in clinical trials pursuant to an investigational device exemption (IDE) from the FDA was seen by Medicare as an indication that the device was experimental, and these devices were not covered under the Medicare program until receiving final PreMarket Approval or clearance under section 510(k) of the Federal Food, Drug and Cosmetic Act. This policy was not established so Medicare could avoid paying claims, but to protect beneficiaries from services that had not been found to be safe and effective.

Medicare's policy of not covering investigational and experimental devices is longstanding and, in fact, stems from the inception of the program. A letter to the fiscal intermediaries in January of 1971 clearly explained the policy. It stated the following:

> "Since the beginning of the Medicare program the Bureau of Health Insurance has tried to emphasize to physicians and beneficiaries that our decision to deny payment for a particular medical item or service because it is considered experimental or investigational is not a judgment that a physician's choice of treatment is inappropriate or that a patient does not need treatment. These decisions are, first, required of us by the law (section 1862(a)(1) [of the Social Security Act]) and are based on qualified medical advice that the items and services have not been generally accepted by the professional medical community as effective and proven treatments . . ."

Medicare's program instructions on medical devices, which were governing until November 1, 1995, were added to the Medicare Hospital Manual, the Carrier Manual, and the Intermediary Manual in 1986. These instructions stated clearly that "medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary". The instructions went on to explain that payment would not be made either for the devices or the procedures and services performed using the devices. Additional instructions in these manuals dealing more generally with all noncovered services also state that any services related to a noncovered service are excluded from coverage.

I would like to emphasize that HCFA was clear from the start about its policy regarding both coverage of investigational devices as well as any related services. To provide an example of how the policy was designed to work—if a hospital admission was solely for the purpose of implanting an investigational device, no payment would be made for the hospital stay. On the other hand, if a patient was admitted for chest pain, but it was decided during the visit to implant an investigational device, Medicare would pay for a medical admission recognizing the chest pain, but Medicare would not pay the much higher rate applicable to a surgical stay. No pay-

ment would be made for services associated with the surgical procedure to implant the investigational device.

This payment policy was designed to protect beneficiaries against the use of devices that the FDA had not found to be safe and effective and devices that had not yet been generally accepted by the medical community. Not all devices that are available on a limited basis subject to an IDE in a clinical trial are ultimately approved. Problems are sometimes discovered in the course of the clinical trial, and some devices fail ever to receive final FDA approval.

New Coverage Policy for Investigational Devices

As you are aware, however, HCFA carefully reevaluated its coverage policy for investigational devices last year. We considered the rapid rate of technological change and improvements made to medical devices that exists today and examined with the FDA the plausibility of creating a mechanism to distinguish among different types of devices with IDEs. As a result, HCFA issued a final rule on September 19, 1995 that would allow for expanded Medicare coverage of investigational devices. This rule was effective for services performed on or after November 1, 1995.

HCFA and the FDA entered into an interagency agreement to establish a process for placing devices with IDEs into one of two categories based on level of risk. The first category (Category A) is for novel, first-of-a-kind devices for which "absolute risk" of the device type has not been established. The second category (Category B) is for devices for which the underlying questions of safety and effectiveness have been resolved for that type of device. These devices are often newer generations of already proven technologies or replications of existing devices by other manufacturers. Under the new policy, Medicare may now cover items and services associated with the use of a Category B device within the context of the FDA approved clinical trial, as long as the device meets other Medicare coverage criteria.

Given the fact that a mechanism could be created to distinguish between level of risk, HCFA determined that some, but not all, devices could be covered without compromising patient safety and should be made available to Medicare beneficiaries who wanted to participate in clinical trials.

I would like to emphasize that this change is a new policy. It is not retroactive and has no bearing on past billing practices. We continue to believe that the prior policy, which was designed to protect beneficiaries against devices that the FDA had not found to be safe and,effective, was the best approach available at the time.

Inappropriate Payments Made to Hospitals Prior to November 1995

I would now like to address the issue of inappropriate payments made to hospitals for investigational devices furnished prior to last year's final rule. Please note that there is ongoing litigation between the Department and 25 hospitals related to the hospitals' claim that the Secretary failed to comply with the requirements of the Administrative Procedures Act in issuing policy in this area. I cannot comment on issues related to this litigation.

Assertions from Hospitals Related to Policy

As you know, the Office of Inspector General (OIG) has uncovered cases where erroneous payments were made for items and services related to the implantation of investigational devices. In response to the OIG investigation, hospitals have made various statements about our policy and the cause of the overpayments. Some hospitals have stated that HCFA's policy was unclear, and others have stated that they did not know about it. As I stated before, however, the policy was plainly contained in Medicare's manual instructions, including the Hospital Provider Manual. That manual explains and interprets the statute and the rules on coverage, payment, and billing that govern operation of the program, and hospitals know that these rules are binding.

If hospitals felt that the policy was unclear, we believe they should have made attempts to discuss it with HCFA. On any issue of uncertainty, providers are encouraged to seek clarification from us. Conversely, if the policy is clear but providers disagree with it, the proper course of action is the same—to contact HCFA. We are always willing to investigate and reevaluate a policy issue brought to our attention by concerned parties.

Payment Integrity

The Medicare system is highly complex and deals with a large volume of individual claims. In FY 1995, the fiscal intermediaries processed 133.3 million bills. HCFA tries to ensure that its policies are being implemented correctly through focused payment safeguards efforts, such as prepayment review, postpayment review, and audits. And, as I will address in a few minutes, we support other payment integrity ideas that would require legislation.

We are disturbed that improper payments were unknowingly made by Medicare for investigational devices and that these improper payments went undetected for so long. However, we are also disturbed that providers continued to bill us despite the fact that it was clearly contrary to our written policy. Avoiding improper payments in the Medicare program depends heavily on the integrity of providers to bill us responsibly and honestly. The situation Medicare faces is similar to that of the Internal Revenue Service in administering the tax system. We expect providers to adhere to the rules stipulated in the manuals and to contact us if they do not understand them or if they are unsure of their responsibilities.

Finally, I want to make clear that hospitals were not confronted with the dilemma of having to bill illegally in order to receive payment for implanting devices. We believe that in almost every instance in which an investigational device was provided, hospitals instead could have furnished an approved device, legally billed Medicare for it, and received payment. The choice they made, however, was to bill improperly for devices that were part of a clinical trial and therefore not covered.

Overpayment Recovery

If Medicare paid claims that were billed inappropriately—in this case for medical devices that had not been approved by the FDA—those payments constitute overpayments that are subject to recovery by HCFA. We are already at work identifying overpayments, and we expect to seek recoveries in accordance with the Debt Collection Act and the Medicare Act. This effort will help to ensure the integrity of the program.

I would like to point out, however, that we may be limited in our overpayment recovery efforts by the level of resources available. Current funding to pursue payment safeguards activities is inadequate because the continuing resolution provides resources at last year's level despite the continuing increase in the volume of Medicare claims. There appears to be growing support in Congress for the need to invest in payment safeguards, and we hope that funds will be appropriated at a level commensurate with the importance of this activity and its anticipated payoff.

Proposed Legislation

I would like to close by commenting on various legislative proposals to strengthen our payment safeguards efforts, including overpayment recovery.

While Medicare's payment integrity activities are improving, they need further improvement, and we look forward to working together on this subject with this Subcommittee and others in Congress. To ensure effectiveness of our payment integrity activities, they need stable and reliable finding. The President and Congress have addressed this need by including in various balanced budget plans a provision that would provide stable funding for payment integrity activities, and we urge you and your colleagues to retain such a provision in any further Medicare legislation.

Conclusion

I am happy to be here today to discuss this important issue. I want to stress again that we should not take lightly the fact that hospitals were consistently billing Medicare and receiving overpayments for care and services related to investigational devices. We hope that situations such as this can be avoided in the future through both our reliance on the integrity of providers and the strengthening of our payment safeguard efforts.

Thank you. I will be happy to answer any questions you may have.

Chairman ROTH. Now, Mr. Ault, when I say you—your agency—are responsible for administering the Medicare program. Your agency sets the policies under which Medicare payments are made. Are you and your contract intermediaries ultimately responsible for ensuring that Medicare's payment polices are complied with?

Mr. AULT. Yes, Senator, we and our contract intermediaries are clearly the first line of defense in making sure that our policies are complied with. I would like to point out that in this particular situation it was an employee with our contractor in Washington State that found something suspicious in reviewing a hospital's bills. The fiscal intermediary in our Seattle regional office, when this was discovered in April of 1993, immediately followed up with a focused medical review that took place over the next 3 or 4 months. In the Fall of 1993, HCFA had sufficient information, and we were al-

ready talking with the Office of Inspector General about this case. And you know what has followed since.

Yes, we clearly do take seriously pursuing fraud and abuse and making the proper payment.

Chairman ROTH. Let me make this observation. I was concerned that the IG said it takes 5 years to complete an investigation. Somehow that is not satisfactory because if it takes 5 years to complete the investigation, does not that permit practices that are undesirable to continue?

Mr. AULT. While it may take a long period of time to complete an investigation of fraudulent activities that involve the Inspector General, and perhaps the Department of Justice or the U.S. Attorneys, that does not mean that we are continuing to make erroneous payments during that period of time. And, in fact, a fraud alert was issued in the Spring of 1994 on this issue. Our contractors were alerted to the abuses in this area and I think we have taken effective action.

Mr. KAVANAUGH. And certainly the IG did not say that the case normally takes 5 years. He said that some cases could take as long as 5 years.

Chairman ROTH. In the instant case, you say you issued some kind of a warning?

Mr. AULT. Yes. We issued a fraud alert to all of the Medicare contractors that there were some billing abuses——

Chairman ROTH. Is that the intermediaries or the actual providers? What do you mean by the contractors?

Mr. AULT. Pardon me. The fiscal intermediaries that process the bills were alerted to be on the lookout.

Chairman ROTH. Was that put in writing?

Mr. AULT. Yes, it was.

Chairman ROTH. Would you submit that for the record?

Mr. AULT. Yes, I will.[1]

Chairman ROTH. Did your policy, as the hospitals have contended, unfairly deny Medicare patients the latest state-of-the-art cardiac care?

Mr. AULT. No, Senator, I do not believe that our policy denied high-quality care to Medicare beneficiaries. In fact, the policy was designed to protect Medicare beneficiaries by clearly stipulating that only services and devices that had been found to be safe and effective could be used. We rely on the FDA, which has the responsibility for making these determinations.

I would further note that clinical trials, by their very nature, are limited. Clinical trials occur in a very few places with a limited number of patients under a strict research protocol. During the time that clinical trials are in place, most patients are being treated by approved devices that are already available and that are providing high-quality care.

Chairman ROTH. One of the claims by the hospitals is that HCFA's policy was vague and unclear. Now, if that were true—and I know you disagree with that statement—could not they have contacted the agency or their intermediaries for clarification?

[1] The document was marked Exhibit No. 14 and can be found on page 104.

Mr. AULT. They most certainly could have and, in fact, we get many questions every day in the central office, our regional offices, and our fiscal intermediaries, and we do answer those questions on the telephone and in writing.

I would also emphasize that this policy was in the hospital manual.

Chairman ROTH. Mr. Ault, is it correct that all patients receiving an investigational device must sign a separate patient consent form and, if that is true, should that form be kept in the patient's medical chart where it would be readily available for a Medicare auditor?

Mr. AULT. Yes. Patients participating in clinical trials must sign a patient consent form because there is some inherent risk, obviously, in trials. It is also true that consent forms should be maintained in the medical record. Our rules require that all pertinent information be contained in the patient record.

Chairman ROTH. And this would certainly be pertinent information?

Mr. AULT. It absolutely would be. It is pertinent both for proper payment and it is pertinent for quality patient care.

Chairman ROTH. Is it not true that the November 1995 policy change has no effect on procedures which took place prior to that date and were then billed to Medicare? In other words, the change of policy was prospective and not retroactive?

Mr. AULT. That is correct. It was prospective only and had absolutely no effect for the past, or for the period we are talking about in these overpayments.

Chairman ROTH. And does the fact that you issued this policy change indicate that the previous policy was wrong or inappropriate?

Mr. AULT. No, I do not believe it does. The purpose of the previous policy was, again, to protect beneficiaries and assure that they received only safe and effective treatments. We examined which medical devices were approved by the FDA for these clinical trials. In reviewing this with the FDA last year it was determined that, given the rapid rate of current technological change with these kinds of devices, and with newer generations coming out, it would be possible to create a sub-categorization and to have two categories. One category was for devices that continued to pose significant risk and for which the fundamental safety and effectiveness had not been determined. A second category included devices for which the fundamental safety and effectiveness had been determined. We are also looking at a generational change.

It is only the second category of devices that we are covering or may cover. Devices still have to meet other requirements, and the patient still must agree to participate in a clinical trial and sign a consent form.

Chairman ROTH. I would just make the observation that change of policy is not unique to Medicare. Certainly the IRS, the Department of Defense and others, from time to time, change policies. That does not necessarily make their earlier policy incorrect for those periods.

Mr. AULT. Right, I would agree.

Chairman ROTH. Although I do have to say I am very dismayed by the fact that HCFA could have a clear policy for so many years and yet, the allegation has been made that hundreds of millions of dollars have been billed and paid by Medicare contrary to your policy.

I regret that, as I listened this morning, it seems to me that instead of having a junk-yard bulldog, we have a puppy dog reviewing these matters. And I am concerned by the allegation that there is a culture out there in the health industry that they do not have to be too concerned about what HCFA says and does.

What is your response to that?

Mr. AULT. I am also concerned about this issue. All of us in the Department of Health and Human Services are extremely concerned about fraudulent billing. I think that we have to do everything we can to improve compliance with our rules and regulations. I think you get compliance by making it clear that providers who break the law will get caught and will face consequences.

We have many efforts under way, over the last few years, especially the last couple of years, to improve our prevention and detection of fraud and to work more closely with the Office of Inspector General and the Department of Justice.

I think the way this case has been handled, the way it was uncovered in our Seattle intermediary and regional offices, is noteworthy.

Chairman ROTH. But I do not see how this apparently fairly widespread practice could go on for so long and not be uncovered.

Mr. KAVANAUGH. Senator, I think that——

Chairman ROTH. I am asking Mr. Ault.

Mr. KAVANAUGH. OK.

Mr. AULT. In this case, we do not see claims for pacemakers. What we get from hospitals are claims for hospital stays, and bills for hospital stays. During a hospital stay in some cases, a pacemaker may have been implanted, and as we now know, an investigational pacemaker may have been implanted.

The proper action for a hospital is not to submit a pay claim, but rather to submit a no-pay claim when the sole purpose of the admission was for an investigational device. However, we do not have that information on the claim form. Moreover, as you heard this morning from the first two witnesses, many hospitals took steps to deliberately hide information from the Medicare program and its agents that would be necessary to properly process the bills.

Chairman ROTH. I hear you but the fact is we are talking about hundreds of millions of dollars. The practice is said to be widespread. The fact is that the FDA knew which hospitals were having clinical testing because they had to approve such testing. I am just surprised that the auditors or someone did not pick it up earlier. Now, your intermediaries are presumably your first line of defense, is that not correct?

Mr. AULT. That is correct.

Chairman ROTH. Why were they not able to uncover the depth of the problem or are they part of the problem?

Mr. AULT. No. I do not think they are part of the problem. And, in fact, I do think in this case that they did uncover the depth of the problem. When this was first noticed at one hospital in April

of 1993, the intermediary immediately undertook efforts to see if this was just a one-or-a-two hospital problem, or if it was more pervasive. The intermediary determined that it was more pervasive. Therefore, we proceeded with the fraud alert to all of our contractors, and we also immediately got the Inspector General's Office involved in the investigation.

Mr. KAVANAUGH. Deliberate efforts to deceive are very hard to find. Certainly, we were very heartened that the intermediaries found this problem. We are taking aggressive action to make sure that this does not happen again, and we are certainly pursuing these overpayments.

Chairman ROTH. I just have to observe that when the allegation is made that hundreds of millions of dollars could be misspent and improperly billed, it does not look to me like the system is working very well.

But time is moving on. Again, I will say to you, Mr. Ault, we have some questions that the attorneys for the University of Washington have submitted for you, and under our rules they can be if a majority agrees to it. What I will do is submit them in writing and ask you to answer them within the next several days.[1]

Mr. AULT. That will be fine.

Chairman ROTH. Thank you very much, Mr. Ault and Mr. Kavanaugh.

Mr. AULT. Thank you.

Mr. KAVANAUGH. Thank you.

Chairman ROTH. Now, I would like to call forward Mr. Farrell Maier. Mr. Maier is a hospital billing executive. Mr. Maier, if you would come forward, please?

Would you please stand and raise your right hand. Do you swear or affirm that the testimony you will give this Subcommittee is the truth, the whole truth and nothing but the truth, so help you, God?

Mr. MAIER. Yes, I do.

Chairman ROTH. Thank you, Mr. Maier, please sit down and proceed with your testimony.

TESTIMONY OF FARRELL MAIER, HOSPITAL BILLING EXECUTIVE

Mr. MAIER. Good morning, Mr. Chairman and Members of the Subcommittee, my name is Farrell Maier and I am appearing here today at your request. I am presently employed as Director of Patient Accounts at Hillcrest Medical Center in Tulsa, Oklahoma. I appreciate the opportunity to testify here today concerning possible fraud and abuse issues in billing Medicare for procedures involving investigational medical devices.

My educational background is in business and accounting. Prior to working in the health care field, I spent 5 years working for Price Waterhouse. I am a certified manager of patient accounts and served for 3 years as member of the Board of the Oklahoma Health Care Financial Management Association of the State of Oklahoma.

I started working in the health care field in July of 1986 when I went to work for Baptist Medical Center in Oklahoma City as di-

[1] The documents referred to were marked Exhibits No. 27 and 29 and are retained in the files of the Subcommittee.

rector of the business office. It was in that position in late 1991 that I first became aware of a possible Medicare billing fraud situation involving procedures for certain cardiac investigational devices. This came to my attention when the hospital's director of radiology called me to get approval for a procedure to be performed by a cardiac surgeon in which a non-FDA approved defibrillator would be implanted in a Medicare patient. I denied the director's request.

I told him we could not bill Medicare for the procedure. I knew that Medicare would not reimburse the hospital for the cost related to the procedure to implant an investigational device still in clinical trials.

I was aware that such claims were not billable through my experience with the Medicare manual and through working with an excellent billing supervisor. It was my responsibility to be familiar with the Medicare billing regulations.

A day or two after I denied the initial request to perform the procedure at our hospital I received another call from the hospital's director of radiology. He told me that the manufacturer's representative of this investigational defibrillator insisted that other hospitals were billing and receiving payment from Medicare when they implanted these investigational devices in Medicare patients. I repeatedly requested that the manufacturer's representative call me to discuss his statement that these claims were being paid by Medicare. The representative never called.

After repeated discussions I thought I finally had convinced the cardiac surgeon that my position was correct, that using non-FDA approved devices in Medicare patients would result in a denial of the claim. At this surgeon's request, on December 12, 1991, I wrote a letter explaining the hospital's policy on this issue. I would like to submit a copy of my letter for the record.[1]

In this letter I set forth in clear and concise terms that the policy of Baptist Medical Center regarding billing Medicare for procedures involving investigational devices is to bill them "as 'non-pay claims,' which results in no reimbursement to the hospital." I concluded the letter by stating that "it is illegal to bill Medicare for non-FDA approved procedures and devices . . ."

In early 1992, Baptist Medical Center was visited by a Medicare auditor concerning an unrelated subject. During that audit, I told the auditor I would like to report an issue that involved non-FDA approved investigational devices being implanted in Medicare patients in hospitals that were apparently billing and being paid by Medicare.

I also conveyed to the auditor the pressure I had received from the hospital's medical staff when I refused to authorize the purchase of the investigational devices for Medicare patients or to request reimbursement from Medicare for such procedures. It was a particularly difficult situation when at the same time a representative of the manufacturer of these devices was advising the physicians that other hospitals were billing and being paid by Medicare for these procedures.

[1] The document was marked Exhibit No. 13 and can be found on page 101.

Subsequently I received a number of phone calls from the Dallas Regional Medicare Office inquiring about this issue. Just as I had done with the Medicare auditor I provided the Medicare investigator with the facts as I knew them. I also asked if my reporting of this would really be looked into or just filed away in a drawer.

I was told it may take several years but it, indeed, would be looked at. I was of the opinion I would probably never hear about this issue again.

Needless to say I was surprised and encouraged when I was contacted by your staff and told they were investigating this important issue.

Our health care system is so large and complex that the only hope of having it survive is if the health care professionals who are required to operate within the rules of the system live up to their responsibilities by knowing the law and complying with it. No one can police the whole system. I believe that the integrity of the entire system depends on the integrity of every individual within the system.

I look forward to providing whatever assistance I can to your investigation and will be happy to answer any questions you may have at this time.

[The prepared statement of Mr. Maier follows:]

PREPARED STATEMENT OF FARRELL MAIER

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My educational background is in business and accounting. Prior to working in the health care field, I spent five years working for Price Waterhouse. I am a Certified Manager of Patient Accounts and served for three years as a member of the board of the Oklahoma Healthcare Financial Management Association of the State of Oklahoma.

I started working in the health care field in July 1986 when I went to work for Baptist Medical Center in Oklahoma City as Director of the Business Office. It was in that position in late 1991 that I first became aware of a possible Medicare billing fraud situation involving procedures for certain cardiac investigational devices. This came to my attention when the hospital's Director of Radiology called me to get approval for a procedure to be performed by a cardiac surgeon in which a non-FDA approved defibrillator would be implanted in a Medicare patient. I denied the Director's request. I told him we could not bill Medicare for the procedure. I knew that Medicare would not reimburse the hospital for the costs related to the procedure to implant an investigational device still in clinical trials.

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Subsequently, I received a number of phone calls from the Dallas Regional Medicare Office inquiring about this issue. Just as I had done with the Medicare auditor, I provided the Medicare investigator with the facts as I knew them. I also asked if my reporting of this would really be looked into, or just filed away in a drawer. I was told it may take several years, but it indeed would be looked at. I was of the opinion I would probably never hear about this issue again. Needless to say, I was surprised and encouraged when I was contacted by your staff and told they were investigating this important issue.

Our health care system is so large and complex that the only hope of having it survive is if the health care professionals who are required to operate within the rules of the system, live up to their responsibilities by knowing the law and complying with it. No one can police the whole system. I believe that the integrity of the entire system depends on the integrity of every individual within the system.

I look forward to providing whatever assistance I can to your investigation and will be happy to answer any questions you may have at this time.

Chairman ROTH. Thank you, Mr. Maier.

You were director of the business office for the Baptist Medical Center in 1991?

Mr. MAIER. Yes, that is correct.

Chairman ROTH. In that capacity, I assume you were responsible for reimbursement?

Mr. MAIER. Yes, I was responsible for billing and reimbursement issues.

Chairman ROTH. Was knowledge of the Medicare billing regulations a basic responsibility of your job? And how difficult was that to do?

Mr. MAIER. It was a basic requirement of my job and with the aid of the Medicare billing manual and then the ability to contact our fiscal intermediary at any time with any questions I did not consider it difficult.

Chairman ROTH. And your situation was not unique; that was generally true of people in similar positions; isn't that correct?

Mr. MAIER. I believe that would be true of any manager or director of the business services area.

Chairman ROTH. Just to make sure that we are clear, did you find HCFA's policy on this issue of investigational devices hard to understand, vague or unclear?

Mr. MAIER. Not at all. I found it very clear even to the point that I was adamant that we just absolutely could not bill the claim in question as a for-pay claim.

Chairman ROTH. But you stated that if you were ever confused about Medicare policy that you could go to either HCFA or your intermediary for clarification?

Mr. MAIER. Yes, Senator. In fact, in this very circumstance since my interpretation of the Medicare billing manual was being ques-

tioned by the physicians because of what the manufacturers' representatives had said I, indeed, called Blue Cross and Blue Shield of Tulsa who was the fiscal intermediary for Baptist Medical Center and I did inquire as to the interpretation that I was making if it was correct or incorrect.

I was told by one of the managers at Blue Cross and Blue Shield of Tulsa that my interpretation was correct and if I did proceed with billing such a claim with the investigational devices to them and billed it as a for-pay claim that it would be considered Medicare fraud.

Chairman ROTH. In your experience, are the Medicare intermediaries an effective first-line of defense in combatting fraud and abuse?

Mr. MAIER. I do not think they are as effective as they can be and should be. I think there is work to be done to make it more effective.

Chairman ROTH. This billing practice has been revealed to be a widespread practice. Are you surprised by that?

Mr. MAIER. I guess I might say that I am personally surprised because if I would have been asked to go ahead and do such billing I would have quit my job before I would have billed Medicare and committed Medicare fraud. And I guess what it says, in a way, is there are a lot of people in the industry who just do not have the integrity that they should have.

Chairman ROTH. Mr. Maier, as I have said earlier, Medicare is based on an honor system. And, frankly, no one—HCFA, the Inspector General or the intermediaries—can protect this system if the basic component of honesty is not to be found.

I have to say that I think the vast majority of the people in the industry are honest and I just want to thank you for your leadership and integrity.

Mr. MAIER. Thank you.

Chairman ROTH. I think your testimony has been most helpful and I appreciate your being here today.

Thank you very much, Mr. Maier.

Mr. MAIER. Thank you, Senator.

Chairman ROTH. Our next witnesses are representatives from three hospitals. Patrick Fry is Chief Executive Officer of Sutter Community Hospitals, and Mark Rieger is Assistant Administrator for Hearts and Transplants for Sutter Memorial Hospital. Dennis Stillman is the Associate Administrator for Finance of the University of Washington Medical Center, and Anthony M. Sanzo is President and Chief Executive Officer of Allegheny Hospital.

Gentlemen, as you know, we swear in all witnesses who appear before the Subcommittee so please stand and raise your right hand.

Do you swear or affirm that the testimony that you are about to give to the Subcommittee is the truth, the whole truth and nothing but the truth, so help you God?

Mr. FRY. I do.

Mr. RIEGER. I do.

Mr. STILLMAN. I do.

Mr. SANZO. I do.

Chairman ROTH. Please be seated.

Mr. Fry, we will begin with your statement and then proceed with Mr. Stillman and Mr. Sanzo.

Mr. Fry, would you please proceed?

TESTIMONY OF PATRICK E. FRY, CHIEF EXECUTIVE OFFICER, SUTTER COMMUNITY HOSPITALS; ACCOMPANIED BY MARK W. RIEGER, ASSISTANT ADMINISTRATOR HEARTS AND TRANSPLANTS, SUTTER MEMORIAL HOSPITAL

Mr. FRY. Good morning, Mr. Chairman and Members of the Subcommittee, my name is Patrick Fry and I am the Chief Executive Officer of Sutter Community Hospitals, a not-for-profit health system based in Sacramento, California. I am joined this morning by Mark Rieger, Assistant Administrator for Heart and Transplants for Sutter Memorial Hospital.

You have asked us here to discuss the issue of Medicare coverage for investigational devices, such as state-of-the-art pacemakers. As you know, we have fully cooperated with your inquiry and look forward to resolving this issue so we may continue to focus on our mission—to provide the highest quality of care to meet the needs of the members of our community.

Mr. Chairman, I do have a longer written statement which I would like to have entered into the record.

Chairman ROTH. Without objection.

Mr. FRY. Mr. Chairman, I first became aware that there was an issue concerning Medicare reimbursement of these cardiac devices in April of 1994. I received a phone call from a cardiac surgeon who was a former chief of staff of the hospital inquiring as to Sutter's experience with investigational cardiac devices. I requested my assistant, Mr. Rieger, to look into the issue and provide me with a response. Mr. Rieger's preliminary findings resulted in his memo of April 13, 1994, which the Subcommittee has reviewed.

This memo provides a snapshot of the issues as relayed to Mr. Rieger by a brief conversation with one staff person, one or two physicians and no other research. It was a hurried response to my question.

Unfortunately I did not spend much time reviewing it. At that time I understood from Mr. Rieger's memo that this was an issue which had a number of confusing aspects to it. To me the memo outlined an issue which we had to do further investigation, review and possible corrective action.

I believed that Mr. Rieger was going to do these things and then follow up with me. Before Mr. Rieger completed his review of this issue and before I had taken any further action, Sutter Memorial Hospital received on June 6, 1994 a subpoena from the OIG's office.

Since then I have kicked myself every day for not appreciating the full significance of this issue. And I wish I had reacted more quickly to address this situation.

I think it is important to note that the policy at Sutter is to follow the best clinical judgment of our doctors so that our patients receive the highest quality, most cost-effective care. The use of these newer devices was recommended by our physicians and all their patients who received them agreed to their use.

All of these pacemakers and defibrillators were approved by the Food and Drug Administration for the use in clinical trials, as

HCFA has acknowledged the importance of these devices by recently clarifying that they will be reimbursed under Medicare.

This action provides access for all our patients, Medicare or otherwise, to the newest pacemakers or defibrillators developed by U.S. companies. The result is a significant quality of care and quality of life improvement for our patients and their families. It also often represents a cost savings to the Medicare beneficiaries and to the program.

Furthermore, there is no financial incentive for Sutter to use one device over another model. If patients receive the state-of-the-art pacemakers, for example, Medicare pays no more than if a less sophisticated device were used. In fact, the use of cardiac devices, investigational or otherwise, represents less than 1 percent of the total revenue for Sutter Memorial Hospital.

In the past, there has been a great deal of confusion over the issue of Medicare coverage for these devices. Over the years the Health Care Financing Administration has issued contradictory directives on the reimbursability of investigational devices.

This issue has been further complicated by the fact that for many years HCFA paid Sutter Memorial Hospital and many other hospitals nationwide for care associated with investigational devices. Nonetheless, the Federal Government has made it clear to us that it does not believe the hospital was entitled to reimbursement for these procedures. Whether or not reimbursement was appropriate is a complex issue. In fact, that very issue is at the heart of an ongoing litigation in court in Los Angeles.

We chose not to join the litigation against Secretary Shalala. In fact, we have chosen to avoid litigation entirely.

At Sutter Memorial Hospital we have only one mission—to provide the highest quality of patient care to the young and old, rich and poor, alike. That is why yesterday Sutter agreed to settle all civil and administrative claims the Federal Government might have against the hospital in connection with investigational devices.

Under the terms of the agreement, Sutter Community Hospitals has agreed to pay the government approximately $1.3 million to resolve this matter. Sutter agreed to this settlement because we do not want to spend time and scarce resources on a potentially long, costly legal process.

We believe this agreement is in the best interest of our hospital and our patients. We were pleased to put this complex and confusing issue behind us so that we can remain focused on our mission—providing the highest quality of care for the communities we serve.

I regret any mistakes that may have been made by our institution for seeking reimbursement from Medicare for these devices.

I take this issue very seriously and take pride in the fact that I work for a not-for-profit hospital whose interests lies in providing high-quality clinically necessary services to our community.

I appreciate the opportunity to present our statement. I, along with Mr. Rieger, appear here today to cooperate fully and would be happy to answer any questions you have.

Thank you very much.

[The prepared statement of Mr. Fry follows:]

PREPARED STATEMENT OF PATRICK E. FRY

Good morning Mr. Chairman and Members of the Subcommittee. My name is Patrick Fry and I am Chief Executive Officer of Sutter Community Hospitals in Sacramento, California. I am joined this morning by Mark Rieger, Assistant Administrator for Hearts and Transplants for Sutter Memorial Hospital.

You have asked us here to discuss the issue of Medicare coverage for investigational devices, such as certain pacemakers. This is an important topic that you have chosen to address, and we appreciate the opportunity to present our views. As you know, we have fully cooperated with your inquiry and look forward to resolving this issue so we may continue to focus on our mission—to provide the highest quality of care to meet the needs of the members of our community.

Let me begin by providing an overview of our health care organization. Sutter Community Hospitals of Sacramento is a not-for-profit health care provider that has offered acute care services to our community since 1923. Comprised of Sutter General Hospital, Sutter Memorial Hospital and Sutter Center for Psychiatry, Sutter Community Hospitals provides a broad array of high quality inpatient and outpatient services designed to meet the health care needs of the greater Sacramento region. Recognized as the leading employer in Sacramento, Sutter Community Hospitals employs nearly 4,000 employees.

As a private, non-profit provider, Sutter Community Hospitals operates solely for the benefit of the communities we serve. Our hospitals serve a broad cross section of the population and provide health care services to people regardless of their ability to pay. If there are any revenues in excess of expenses, they are reinvested in hospital care and community benefit services. There are no dividends paid out to shareholders because there are no shareholders. In 1995, our community-based 15 member board of trustees adopted this mission statement: "Sutter Community Hospitals exists to provide primary, tertiary and a continuum of services to meet the health care needs of the people living in the greater Sacramento area and throughout Northern California. We seek to be the provider of choice to our patients, partner of choice to physicians and payors, and the employer of choice to our staff."

Sutter Community Hospitals also offers a full complement of community benefit programs ranging from traditional charity care to educational programs focused on health promotion and disease management. Each year we conduct a community needs assessment, then create a plan and implement a strategy to address those needs. In 1994, the last year for which we have reported data, Sutter Community Hospitals provided nearly $27 million in community benefit services. These services included clinical research and community health education, indirect and in-kind support to community organizations, charity care, and the unpaid costs of public programs including Medicare, Medi-Cal and local medically indigent adult programs.

Over the years, Sutter Memorial has taken the lead in women's health, oncology, cardiology, perinatology and pediatrics. Sutter Memorial Hospital serves more than 750,000 people and provides care to more than 60,000 patients on an annual basis. Of the 7,000 babies born annually at Sutter Memorial, 60% are Medi-Cal. Sutter Memorial Hospital is a disproportionate share provider, serving a larger portion of the medically indigent, and serves as the community's only neo-natal Intensive Care Unit and special care nursery. Sutter Memorial Hospital is also the largest regional referral center for cardiovascular disease diagnosis and treatment in Northern California and, in an analysis of our Medicare data, has been recognized as among the top hospitals in the country in providing the best outcome from heart surgery.

Sutter Memorial Hospital has also been recognized as a leader in providing quality care by the Joint Commission on Accreditation of Healthcare Organizations. In its most recent evaluation, Sutter Memorial Hospital received an Accreditation with Commendation, the highest level of recognition attained by only 3% of hospitals nationwide. But perhaps most importantly, Sutter Memorial Hospital has been recognized as a quality health care provider by our patients. Ninety-five percent of Sutter Memorial's patients are satisfied with their overall hospital stay. In addition, recent market surveys prove that our community prefers Sutter Memorial Hospital over other facilities for their health care services and ranks our hospital the best provider of heart services.

I take great pride in the fact that Sutter Community Hospitals is a non-profit, health care provider focused on delivering high quality, clinically necessary health care services to meet the needs of the communities we serve.

I became the Chief Operating Officer of Sutter Community Hospitals and Administrator of Sutter Memorial Hospital in December of 1993. My colleague, Mark Rieger, was officially appointed Assistant Administrator of the Hearts and Trans-

plant Services in early March, 1994. I first became aware of the issue of Medicare coverage for investigational cardiac devices in April of 1994.

As you may know Mr. Chairman, in the past, there has been a great deal of confusion over the issue of Medicare coverage for these devices. Over the years the Health Care Financing Administration (HCFA) has issued contradictory directives on the reimbursability of investigational devices. This issue has been further complicated by the fact that for many years HCFA paid Sutter Memorial Hospital and many other hospitals nationwide for care associated with investigational devices.

Why has the issue of reimbursability of investigational devices been confusing? By statute and regulation, Medicare covers all services which are "reasonable and necessary." The digest of Medicare's specific coverage policies contained in the hospital manual is silent on investigational devices. And HCFA has previously approved reimbursement of these devices on a case-by-case basis. In 1986, a two-line sentence in a 15-pound policy manual referenced that Medicare would not reimburse for devices not approved for marketing by the FDA. Then, in 1989, HCFA attempted to clarify their position and issued a proposed regulation outlining their reimbursement policy for investigational devices; but that regulation was never finalized. At the same time, in many regions of the country, fiscal intermediaries continued to make payments for services related to investigational devices. HCFA's policy was so misunderstood and unclear that it required the agency to issue a "compilation and explanation of existing policies" to its intermediaries in December of 1994. Even with these directives, and careful scrutiny of claims by intermediaries and PROs, Medicare paid the overwhelming majority of claims for services provided with these devices. Finally, in 1995, HCFA once and for all clarified their position through final regulations, broadly disseminated through publication in the code of regulations, extending coverage to approximately 95% of investigational devices.

We are pleased that HCFA has reaffirmed Medicare coverage for almost all investigational cardiac devices. The use of these devices has a clear quality of care and quality of life impact on the many senior citizens, our patients, who receive them. This action provides access for all our patients, Medicare or otherwise, to the newest pacemakers or defribillators developed by U.S. companies.

Although these cardiac devices, such as pacemakers and implanted defribillators are called "investigational," they are not experimental. In fact, the safety and efficacy of these devices has been established. These devices are incremental improvements of long-established and accepted medical technology. (For example, there may be new leads placed in a pacemaker or a new battery to make it last longer; yet both of these improvements would cause the FDA to require the device to be labeled "investigational.") These incremental improvements often make a huge difference in patient care and comfort. A patient who receives these newer devices faces a lower mortality and morbidity risk, a shorter length of stay in the hospital, and a quick return to productivity. Many of these newer, and smaller, devices can actually be implanted intravenously instead of through an open chest procedure for which the chance of complications and death are higher and for which the hospital stay and recovery is much longer. The result is a significant quality of care and quality of life improvement for our patients and their families. It also often represents a cost savings to the Medicare beneficiary and to the program.

I realize that you have not asked me here today to find out about patient care, but, I think it is important to note that the policy at Sutter is to follow the best clinical judgment of our doctors so that our patients receive the highest quality, most cost effective care.

The use of these newer devices was recommended by our physicians and all their patients who received them agreed to their use. All of these pacemakers and defibrillators were approved by the Federal Food and Drug Administration for use in clinical trials. And, HCFA has acknowledged the importance of these devices by recently clarifying that they will be reimbursed under Medicare.

Under the prospective payment system (PPS), Medicare pays only a flat amount per diagnosis, regardless what type of device is used. Even today, Medicare's billing instructions for investigative devices remains vague—there is no separate code on the bill to reflect charges for investigative devices. If patients receive state-of-the-art pacemakers, for example, Medicare pays no more than if a less sophisticated device were used. Consequently, there is no financial incentive for Sutter to use one device over another model. In fact, the use of cardiac devices, investigational or otherwise, represents less than 1% of total net revenue for Sutter Memorial Hospital.

I first became aware that there was an issue concerning Medicare reimbursement of these cardiac devices in April of 1994. I received a phone call from a cardiac surgeon, and former chief of staff at the hospital, who was inquiring as to Sutter's experience with investigational cardiac devices. Before this phone call I had no knowledge or awareness of any issues concerning the use of investigational devices at Sut-

ter Memorial. I requested my assistant Mr. Rieger to look into the issue and provide me with a response. Mr. Rieger's preliminary findings resulted in his memo of April 13, 1994, which the Committee has reviewed. This memo provides a snapshot of the issue as relayed to Mr. Rieger by brief conversations with one staff person, one or two physicians, and no other research. The memo was a hurried response to my question. Unfortunately, I did not spend much time reviewing it. At the time I understood from Mr. Rieger's memo that this was an issue which had a number of confusing aspects to it. To me this memo outlined an issue on which we had to do further investigation, review and possible corrective action. I believed that Mr. Rieger was going to do these things and then follow up with me. Before Mr. Rieger completed his review of this issue, and before I had taken any further action, on June 6, 1994, Sutter Memorial Hospital received a subpoena from the OIG's office.

Sutter Memorial Hospital was not the only institution confused regarding the issue of Medicare coverage for investigational cardiac devices. Indeed, 131 other prestigious healthcare facilities from across the country, some large and some small, some renowned such as Johns Hopkins and Cedars-Sinai, and others not so well known, received a subpoena. Even the U.S. Congress recognized that the HCFA policy concerning Medicare coverage for investigational devices needed clarification as demonstrated by legislation introduced by your colleagues, Senator Hatch (S. 955) and Congressman Thomas (H.R. 1744), that has attracted over 20 cosponsors in the Senate and over 50 cosponsors in the House.

Nonetheless, since June 1994, I have kicked myself everyday for not appreciating the full significance of this issue and for not taking faster action to address this situation. I wish I had focused on this issue in the 6-week period between when I first became aware of the situation and before the OIG subpoena. In the course of running a $700 million health care organization, however, I did not spend enough time reviewing Mr. Rieger's memo, nor did I appreciate the full scope of the issues or the implications presented in it. I understood from the memorandum that we were at risk—reimbursement could be denied. The fact that we were at risk of being denied reimbursement of these necessary services from Medicare is a fact that we and all hospitals encounter on a dally basis with the Medicare program.

As a result of this controversy, we have carefully reviewed our clinical trials policy and dramatically increased oversight of our research programs. This action includes increased administrative review, legal review, and billing review of all clinical trials that occur within our institutions throughout the region. It is an enhancement of our previous system and the detailed information on how this process works has been communicated and discussed with every member of our staff involved in these issues. Finally, we have a long-standing and thorough patient care review process.

I urge the Committee not to lose sight of the patient care issues surrounding the use of investigational devices. These cardiac devices have proven to be life saving and improve the quality of life of our most frail senior citizens. In the physicians' judgment, these devices have been essential to their patient's life. Clearly, the physicians' judgment has not fallen on deaf ears. These devices have been determined to be "reasonable and necessary" as is evident with HCFA's recent promulgation of new regulations that specifically allow for the reimbursement of costs for the same type of devices Sutter provided to its patients. Indeed, we are delighted that HCFA has reached this conclusion and agrees that nearly all investigational devices are reimbursable.

I regret any mistakes that may have been made by our institution in seeking reimbursement from Medicare for these devices. I take this issue very seriously and take pride in the fact that I work for a non-profit company whose interest lies in providing high quality, clinically necessary services to our community.

I hope I have given you a view of what Sutter Memorial Hospital and Sutter Community Hospitals are like—the patients we serve and the community benefits we deliver. This view is meant to give you a sense of our commitment in providing the very best medical care and the dedication to continuous improvement in the quality of that care.

I appreciate the opportunity to present our statement. I along with Mr. Rieger appeared here today to cooperate fully and would be happy to answer any questions you or the other Senators might have. Thank you.

Chairman ROTH. Mr. Stillman?

TESTIMONY OF DENNIS STILLMAN, ASSOCIATE ADMINISTRATOR FOR FINANCE, UNIVERSITY OF WASHINGTON MEDICAL CENTER

Mr. STILLMAN. Mr. Chairman, Members of the Subcommittee, ladies and gentlemen, my name is Dennis Stillman and I am the Associate Administrator of Finance at the University of Washington Medical Center in Seattle.

I am the Medical Center's chief financial officer. I have worked for the University of Washington since 1987. The University of Washington Medical Center is a publicly owned, nonprofit agency operated by the State of Washington. All employees of the university, including me, are government employees.

The Medical Center cares for patients throughout the Pacific Northwest, trains doctors and other health care professionals for Washington, Alaska, Montana and Idaho, and engages in related medical research as a teaching hospital.

Our mission is to provide the highest achievable quality of care, one that sets a single standard for all of our patients and serves as a model for the health care professions at large. Our patients are treated in a non-discriminatory manner regardless of age, sex, income or color.

I am here today to talk about the University of Washington's efforts to enhance the level of care and improve the quality of care and delivery of good medicine to our patients. I am not a physician. When I met with the Subcommittee staff, in advance of my testimony today, it was made clear that staff does not want to focus on the medical benefits of the treatment at issue. But the fact remains that we cannot separate the propriety of the billings from the clinical care provided.

Under the Social Security Act, Medicare payments may be made for those services which are medically reasonable and necessary. Medicare recognizes that providers of cardiac services are entitled to compensation for treatment which meets that standard.

Specifically, I am talking about implantable, defibrillator systems, known as "IDS." I will illustrate my remarks with an example.

Let us assume, Mr. Chairman, that a resident or visitor to Seattle loses consciousness from cardiac arrest. Paramedics respond to this aid, resuscitate him with electric shock, and transport him to the University of Washington Medical Center.

There, one of our internationally recognized cardiologists diagnoses his illness as sudden cardiac death syndrome, or "SCD," a life threatening condition. The doctor, choosing among various therapies, may recommend the implantation of a combination pacemaker/defibrillator.

Prior to 1989, the University of Washington Medical Center would have implanted in our patient a device known as an Automatic Implantable Cardioverter Defibrillator, or "AICD," a recognized therapy reimbursable under Medicare and Medicaid programs. The AICD was implanted in patients by cracking open the patient's chest, pulling back the rib cage, and physically attaching wires to the heart of the patient and implanting the device in the abdominal cavity, with all the risks attending major surgery.

The way the device functions is to monitor the heart beat, and, in response to adverse changes in heart rhythm, it administers a 750-volt shock which has been compared to that of the kick of a mule. Unfortunately, the AICD was not able to distinguish well between unusual heart activity due to exertion or a life-threatening arrhythmia. In other words, the AICD could not tell whether you were engaging in physical exercise, like climbing stairs, or having another cardiac arrest. You could get shocked either way.

As a result, patients lived in constant fear that even moderate exertion or minor heart rhythm irregularities would result in a massive shock.

In late 1989, the Medical Center began using an improved device known as a Pacer Cardioverter Defibrillator or "PCD." I have with me the actual devices and a comparison photograph of three generations of the Implantable Defibrillator Systems so you can see what I am talking about.

The first device, on the left, and I believe we provided photographs in the testimony, was the AICD, that was the approved device prior to 1989. The middle on this chart is the PCD, which we used in 1990, and the third device is the device currently being used.[1]

As you can see the devices are getting progressively smaller. But the improvements are much more than physical. The benefits of the PCD are dramatic. First, the implantation no longer requires open chest surgery and all the attendant risks, which produced a mortality rate with the ACID of about 7 percent. The device no longer requires attaching wires directly to the heart muscle. The PCD can control heart rhythm with a jolt of only 5 volts.

It also has a much better monitoring capability and is able to distinguish between cardiac distress and moderate exertion. These are just a few of the improvements and the advantages over the older generation of implantable defibrillators which the PCD offers to patients suffering from Sudden Cardiac Death syndrome.

Much has been said about the HCFA manual provision which supposedly prohibited hospitals from receiving payment for procedures employing devices which had not received FDA approval for marketing. These devices, all of these devices, are now fully approved by the FDA.

It was our understanding that this provision was a non-binding directive to HCFA intermediaries which permitted discretion and differing interpretations around the country and was, as a practical matter, applied on a case-by-case review of individual patient records in determining the medical necessity of the treatment provided.

In fact, Medicare subsequently audited several of our claims, specifically looking at these devices, and specifically mentioning that these may be excepted from Medicare coverage, and determined that the implantation of the PCD was medically necessary and approved the claims for payment.

The billing issue first came to the attention of the University of Washington Medical Center in January of 1990 when one of our

[1] The document referred to was marked Exhibit 19 and is retained in the files of the Subcommittee.

staff members advised that she did not believe that Medicare would pay for implanting PCD's in cardiac patients. Our cardiologists were alerted to this issue and discussions followed among the medical staff, including our medical director, as to whether this procedure was medically reasonable and necessary. It was the judgment of the medical staff that the PCD implants met that standard and we continued submitting claims for reimbursement.

We also checked with other hospitals around the country and found that our practice was consistent with theirs in submitting claims for PCD implants.

Based on the system of Medicare reimbursement, we knew that the only way to engage payors in post-procedure review was to submit a claim for services rendered and to encourage discussion between our doctors and nurses and payor medical directors, of the medical necessity of the improved technology.

It is important to keep in mind that the payments received from Medicare for PCD devices were the same as if we had used an AICD and implanted that in the patient.

The device does not determine the propriety of the claim, nor the amount paid. There is no question that the diagnosis of Sudden Cardiac Death syndrome was traditionally recognized as an illness which could be appropriately treated by defibrillation therapies which were reimbursed by Medicare.

Under another alternative we can obtain pre-authorization. A number of payors would do that. Medicare refused to do that. The only way to obtain a determination of coverage from Medicare was to submit the claim for the services and go through retrospective review by Medicare and, if necessary, file an administrative appeal were the claim denied.

With those payors who pre-authorize, we provided supplemental information describing the Implantable Defibrillator Systems and the medical necessity of the treatment and that proved sufficient.

The supplemental information was included in the patient's records and aided those payors, like Medicare, who engage in retrospective review. This enhanced and supplemented the documentation in the medical record which provided full and complete disclosure of the treatment and the technology used.

The fact of the matter is, Mr. Chairman, that this is and was the best treatment available. And it costs the Medicare program no more than if we had stayed with the older devices. We could have continued to use implantable AICD's in treating Sudden Cardiac Death syndrome patients. But good medicine demanded that less intrusive, more efficient, and equally cost-effective improvements be employed for every patient that we see, regardless of how old they are or how rich they may be.

Surely, the Medicare reimbursement policies should not be interpreted to reach a contrary result. HCFA reached the same conclusion last year when it finally promulgated through appropriate, substantive rulemaking procedures a policy consistent with our practices.

While my remarks are necessarily limited by time constraints, I respectfully invite the Subcommittee's attention to the written statement I have submitted on behalf of the University of Washing-

ton Medical Center which goes into greater detail on the points I have touched upon today.

Thank you.

[The prepared statement of Mr. Stillman follows:]

PREPARED STATEMENT OF DENNIS STILLMAN

My name is Dennis Stillman and I am the Associate Administrator for Finance at the University of Washington Medical Center ("UWMC") in Seattle, Washington. I submit this statement on UWMC's behalf based in part on information provided by others at the Medical Center. The UWMC is a publicly owned, nonprofit academic medical center operated by the State of Washington.

I. The University of Washington's Mission

"The primary purpose of the UWMC is to care for patients." That is the first sentence of our mission statement. In upholding it, we embrace our obligation to provide optimal medical care to all of our patients, regardless of their age and regardless of their economic circumstances.

The second sentence of our mission statement reads:

"The Medical Center serves as a teaching and research resource, providing high-quality education for students of the health sciences and an environment in which clinical research may be conducted." Clinical research includes providing patients with access to state-of-the art technology to prolong life and well-being, while decreasing medical costs and patient suffering.

Through the use of medical devices approved for investigational use by the Food and Drug Administration ("FDA"), the UWMC carries out its mission to practice good medicine and provides Medicare and Medicaid patients with the same safe, effective and optimal care that it would make available to any patient needing medical attention, regardless of age or economic status. With regard to the cardiac devices at issue here, UWMC's provision of good medicine cost the government no more money than would otherwise have been spent, visited no additional financial or physical harm upon its patients, and enabled elderly and poor patients with serious, life-threatening illnesses to escape the physical trauma and psychological strain inherent in the use of the older, technologically inferior devices.

II. Sudden Cardiac Death and Implantable Defibrillators

The benefits of these devices implanted in Medicare beneficiaries and Medicaid recipients at UWMC, known generally as Implantable Defibrillator Systems ("IDS"), are impossible to ignore. The trade name for the devices at issue here is "Pacer Cardioverter Defibrillator," or "PCD."

In the mid-1980's, UWMC began treating patients who were at risk for Sudden Cardiac Death syndrome, or "SCD," with IDS's. SCD occurs when the electrical system of the heart malfunctions. The electrical malfunctions can cause uncontrolled, chaotic heart rhythms—ventricular fibrillation or "VF", (which has been likened to converting the heart into a "quivering bag of worms") or a very fast heartbeat—ventricular tachycardia or "VT." When VF occurs, the heart cannot pump blood; VT also severely, impedes the heart's normal function and often degenerates into VF. Because no blood is reaching the brain, patients experiencing VF survive an average of 10 minutes or less; brain injury begins after four minutes. The only way to stop VF is to defibrillate or shock the heart to stop the chaotic pulses and resume normal beating.

Emergency medical professionals use external defibrillators to resuscitate SCD victims. They are successful in fewer than one out of every ten cases even in Seattle, which has the best resuscitation rate in the United States. For those patients fortunate enough to survive a first bout with SCD, recurrence is very likely. A standard treatment for SCD survivors is the implantable defibrillator.

University of Washington Medical Center first used a device with the trade name "Automatic Implantable Cardioverter Defibrillator" or "AICD." Through electrodes attached to the heart, the AICD detected increases in heart rate. After the heart rate exceeded a preset threshold, the then-available AICD would deliver a massive electrical shock (750 volts) to terminate the abnormal rhythm. The AICD could not readily differentiate between unusual heart activity due to exertion or an episode of tachycardia, and treated all such episodes with the same 750 volt shock. A shock of that magnitude is like being kicked in the chest by a mule. Because the shock might be delivered in response to simple exertion or minor heart rhythm abnormalities, patients who received AICD's lived in constant fear of being shocked. This was frequently emotionally devastating. The older-technology AICD was implanted inside the abdomen and the patient's chest was opened (or, in surgical vernacular,

"cracked") to permit the surgeon to sew the electrical sensors or "leads" onto the heart.

Despite these drawbacks and the high cost of the AICD, it was the best available therapy for sudden death survivors. Thus, it was widely used by cardiologists and cardiac surgeons around the country. The Health Care Financing Administration ("HCFA") also recognized the medical necessity of AICD therapy for sudden death survivors. In 1986, HCFA issued criteria that it would examine on a case-by-case basis whether the AICD was medically necessary, and therefore, a covered service.

III. Medical Necessity of the PCD

Because of the AICD's limitations, device manufacturers and scientists at institutions such as UWMC continued to work to improve defibrillator technology. In 1989, UWMC was among the select institutions that participated in FDA-approved clinical trials for the PCD. Doctors across the country immediately recognized that the PCD enjoyed several clear therapeutic advantages over the then-existing AICD's:

1. *Antitachycardia pacing.* The PCD had the ability to distinguish between different types of electrical malfunctions in the heart and deliver appropriate electrical pulses through antitachycardia pacing. This involves the delivery of gentle electrical pulses in lieu of the AICD's 750 volt shock. This spared the patient the physical pain and emotional trauma associated with unnecessary defibrillator shocks, while promptly terminating life-threatening rhythm disorders.

2. *Atrial Fibrillation.* The atrium is the upper chamber of the heart. Atrial fibrillation is a relatively common and non-life-threatening condition. The PCD distinguished between a benign atrial fibrillation and more lethal disorders. The then-current AICD did not recognize this difference, and could unnecessarily deliver a massive shock in response to an atrial fibrillation. This unnecessary shock could actually induce VT or VF.

3. *Smarter Device.* The treating physician could specially program the PCD to accommodate the individual traits of the patient in order to reduce unnecessary shocks and accompanying trauma. It has been estimated that approximately 40% of the shocks delivered by the AICD were unnecessary. With the PCD, the number of unnecessary shocks was reduced to less than 10%.

4. *Faster Device.* During the period in question, the PCD responded much more quickly to heart rhythm changes. The AICD could require from 13 to 20 seconds to deliver the shock. In contrast, the PCD was able to deliver appropriate therapy for VT in less than 3 seconds. The benefit of this difference to a patient whose brain is being deprived of oxygen is obvious.

5. *Less Expensive.* The PCD's battery lasted for approximately 1 year longer than the AICD battery, thereby requiring fewer procedures to maintain its function.

6. *Smaller.* The PCD was smaller than the AICD and therefore was more comfortable for the patient.

7. *Avoid Chest surgery.* In 1989, to implant an AICD's leads, the patient's chest would have to be cracked and the rib cage opened. The PCD's transvenous leads can be inserted through the patient's veins into the heart muscle without the need for this traumatic, expensive and risky surgical procedure.

8. *Bradycardia Pacing.* The PCD doubles as a pacemaker; the AICD did not. Slow heart rate, bradycardia, occurs in about 15% of patients at risk for SCD. Bradycardia is often treated with a pacemaker. Had an AICD been used, the patients in need of a pacemaker would require a second surgery. With a PCD, the pacemaker is integrated into the defibrillator and coordinates the operations of the two functions. When the defibrillator and pacemaker are independent, they do not communicate and occasionally work at cross purposes, potentially giving rise to life-threatening complications.

The UWMC viewed the PCD as the defibrillator of choice. Indeed, UWMC understood that there was near consensus within the medical community that the PCD's represented the best defibrillator treatment available at the time for patients who suffered from SCD. In fact, physicians throughout the Pacific Northwest referred patients to UWMC solely for the purpose of implanting the PCD.

Even the Medicare system recognized patients' medical need for the PCD. In several cases, HCFA's local contractors reviewed UWMC patient medical and billing records specifically to determine the medical necessity of the implanted defibrillator and approved the procedures before making Medicare payments to UWMC.

FDA ultimately granted full FDA pre-market approval to each and every PCD device and lead system used by the UWMC. In other words, FDA ultimately found that all of the PCD devices used in clinical trials at the UWMC were indeed safe and effective.

IV. UWMC's Attempts to Clarify HCFA Policy

Implanting any defibrillator system was not cheap, averaging around $50,000 per patient. UWMC would not absorb the cost of those procedures when defibrillation implantation was a covered service. When we became aware in early 1990 that there was a significant issue as to whether HCFA would reimburse hospitals for the PCD implantation procedure in patients who required the device, UWMC did the only logical thing. We investigated how these claims could be properly paid.

We first told the doctors who performed the PCD implants that there was an issue regarding Medicare coverage for the implants, and that they were to do no more implants without preauthorization from insurers. UWMC encountered little difficulty in obtaining coverage from private insurers. The electrophysiology nurses who were to obtain preauthorization found, though, that the insurers' representatives with whom they spoke were not knowledgeable about the different types of implantable defibrillator systems, and because the acronym "PCD" did not appear on their approval forms, refused to give preauthorization on that basis alone. The nurses found that it was necessary to then speak with the insurers' medical directors who understood the medical necessity of the device and gave the requested preauthorization.

The electrophysiology nurses discovered that it was often impossible to get preauthorization from Medicare and Medicaid. Medicare and Medicaid representatives told the nurses that the government only performs retrospective chart review after the procedure is completed and a claim has been submitted. If the procedure is found to be medically necessary, it would be covered.

For Medicare and Medicaid, though, the only way to communicate medical necessity for the procedure device was through retrospective review of the medical records. To communicate this medical necessity, UWMC doctors and nurses provided supplemental information in the record to explain why the patient required this device.

The type of device actually implanted was always clearly disclosed in the medical records. Again, Medicare paid the charges for PCD implants of patients after reviewing complete medical and billing records for medical necessity. UWMC understood this payment to be a manifestation of reasonable Medicare policy to cover the PCD implant in medically appropriate circumstances.

While the doctors and nurses attempted to educate Medicare and other insurers about the necessity of the PCD device for sudden death survivors, our staff investigated reimbursement practices by other Medicare intermediaries by contacting institutions using the PCD. We telephoned the financial offices of other institutions that were implanting the PCD and discovered that most institutions were unaware of reimbursement difficulties with Medicare for the PCD. One institution reported that it had an agreement with its Medicare intermediary to receive reimbursement for the PCD up to the AICD's cost. This information, coupled with our practice of fully informing Medicare of the medical necessity of the device, our knowledge that Medicare covered implantable defibrillators, and the fact that Medicare routinely audited UWMC and could easily review the charges for PCD implantation procedures and deny them if it so chose, convinced us that if there were any prohibition against Medicare reimbursement, it was non-binding and discretionary based upon medical necessity considerations.

Further, it is important to remember that HCFA reimburses UWMC and other hospitals on the basis of diagnosis-related group codes, or DRG's. Under the DRG reimbursement system, Medicare makes a set payment to UWMC for defibrillator implantation, regardless of which device is used. Because Medic are paid no more for this state-of-the-art technology than it would have paid for the older devices, and because the newer technology represented the best care available for the patients, permitting the doctors to implant PCD's resulted in a win-win situation for HCFA and Medicare patients. Therefore, UWMC proceeded with the PCD clinical trials, and elderly and poor people got the best medical technology available at no additional cost to the government.

V. HCFA's Actions support the Non-Binding Nature of the Policy

UWMC's belief that HCFA's policy was not binding and was flexibly enforced is amply supported by HCFA's own actions.

Before promulgating new regulations in September 1995 (60 Fed. Reg. 48417), HCFA had a variety of contradictory policies on payment for investigational devices. After the passage of the Medical Device Amendments Act in 1976, HCFA articulated the Medicare program's policy of paying for investigational devices and related services as long as they were found to be reasonable and necessary for the treatment of a particular patient. In 1977, HCFA issued instructions to assist Medicare contractors in responding to beneficiaries on coverage matters. The instruction stated

that contractors were to explain to the beneficiary that Medicare pays for a particular medical device or associated service based upon its general acceptance by the professional medical community as an effective and proven treatment for the conditions for which it is being used or, for the rarely used, novel or relatively unknown treatment or service, based upon authoritative evidence of its safety and effectiveness.

In 1986, HCFA transmitted its manual provisions to contractors and hospitals. These manual provisions were never published in the Federal Register with the opportunity for notice and comment. As UWMC understands it, publication is necessary if HCFA wishes to promulgate a substantive, binding rule. Instead, the policy was more of a statement of bias or inclination, which could be overcome with a showing that the service was medically reasonable and necessary.

Three years later, when HCFA published proposed regulations for notice and comment that would have prohibited payment for PCD implantation, they were not adopted. Not until after the Inspector General's subpoena was issued in 1994, with the devastating effect of stopping many clinical trials in the United States and depriving the elderly and the poor of access to the best medical device technology, did HCFA finally adopt a rule. The rule that HCFA did promulgate, effective November 1, 1995, completely rejected the proposed rule of six years earlier and reversed the 1986 manual provisions.

HCFA finally recognized what UWMC and other institutions had always known: the prior policy created a false presumption that all investigational devices were not safe and effective or medically necessary; the policy saved not one penny of government money; and the policy served only to deprive elderly and poor people of access to state-of-the-art medical care with no regulatory benefit.

Since the September 1995 final regulations permitting payment for the devices went into effect, every version of the PCD used by the UWMC was retroactively designated as non-experimental (designated as "Category B") and may now be covered by Medicare when medically indicated. Under the new regulation, each and every procedure for which the UWMC is now being questioned would be covered by both Medicare and Medicaid.

HCFA's more routine auditing functions also support UWMC's actions. The Medicare program periodically audited UWMC's cost reports, but never questioned any charges for PCD implantation. The local Medicare contractors scrutinized UWMC files prior to payment specifically to determine if the PCD implants were medically necessary, and consistently determined that they were. In every such file, the fact that a PCD was implanted was plainly apparent. Medicare utilization review also analyzed many of the files after payment was made, and approved the payments. HCFA's own billing codes did not include a code that a hospital can use to alert HCFA that a device is investigational. When the UWMC billing department specifically requested advice from the local Medicare intermediary about whether it could bill for the PCD, it received an equivocal reply that conflicted with the information UWMC had received from other institutions and then the intermediary continued to regularly pay these claims.

VI. Conclusion

HCFA's own regulatory activities show that UWMC and the other institutions have done nothing but try to practice good medicine regardless of whether a patient was rich or poor, young or old. As noted above, prior to those September 1995 regulations, HCFA had promulgated no final regulations regarding Medicare coverage for investigational devices. HCFA's only pronouncements on the issue were nonbinding, and contradicted by consistent payment. If HCFA's position is that these services were not medically reasonable and necessary, that position is contradicted by widespread medical opinion and, ultimately, by FDA's own findings that the devices are safe and effective and HCFA's September 1995 regulations.

This posture is also at odds with UWMC's legal and ethical mandate to provide all patients, including the elderly and the poor, with the best and safest devices available—the PCD. Further, implanting a PCD was no more expensive than implantation of an AICD, and ultimately resulted in cost-savings to the patient's overall care.

Medical centers such as the UWMC are now being scrutinized for providing optimal medical care in the face of regulatory failure and confusion. Institutions that conduct clinical research to benefit all Americans and maintain the preeminence of our medical technology in the world, should not be deterred from continuing to carry out that mission. They certainly should not be punished for doing what they reasonably believed was in the best interests of their patients and in accord with prevailing law.

Chairman ROTH. The full statement will be included as if read.
Mr. STILLMAN. Thank you.
Chairman ROTH. Mr. Sanzo?

TESTIMONY OF ANTHONY M. SANZO, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ALLEGHENY GENERAL HOSPITAL

Mr. SANZO. Good afternoon, Mr. Chairman, my name is Anthony Sanzo. I am the President and Chief Executive Officer of Allegheny General Hospital in Pittsburgh, Pennsylvania.

I welcome the opportunity to come before the Subcommittee to help clarify Medicare reimbursement issues involving the use of investigational devices to treat Medicare beneficiaries. As you know, this issue has long been surrounded by confusion and uncertainty. Indeed, it has been confusing since the Medicare prospective payment system was established in 1983.

During that time, health care providers have lacked a clear set of rules defining reimbursement for the treatment of Medicare beneficiaries when investigational devices are involved in the course of treatment. It was not until 1995 that providers received clear guidance by regulations promulgated by HCFA.

I would like to take this opportunity to briefly outline the points that I believe are important to this discussion. Let me make just five points.

First, Allegheny has historically committed itself to advancing clinical knowledge. We are proud participants in the FDA approved clinical trials in question. Through our participation in the clinical studies, we were able to provide our patients with new technologies that were obviously and compellingly superior to existing devices. In fact, it was our desire to provide superior care to our patients that dictated the use of investigational devices in question.

In the course of evaluating patients with life-threatening illnesses, it occasionally became apparent that a patient would materially benefit from having such an investigational device. To not use clearly superior investigational devices when warranted clinically would be unethical. Specifically withholding these devices from Medicare patients would be discriminatory and reprehensible.

Second, the use of the term, "investigational," to label these devices must be placed in context. All devices were approved for use in human beings and were sold or given to hospitals for use under the auspices of an FDA-approved clinical trial or trials. In almost all cases, the investigational devices were new generations of existing technologies and incorporated improved design and technology.

Third, since 1983, Medicare has been paying hospitals on a prospectively established case payment for inpatient care, regardless of the cost incurred by hospitals in providing that care.

Therefore, Allegheny's payment for the services involving the use of the devices under FDA-approved clinical trials was the same as our payment would have been if we had implanted the clinically inferior devices previously approved by the FDA.

Fourth, Allegheny made a good faith effort to understand and to comply with HCFA guidelines regarding reimbursement for the investigational devices.

Approximately 130—and today I heard 132—of some of the finest medical centers in the country find themselves in the same situation. This is, clearly, not an Allegheny-specific issue.

Finally, HCFA's policy on this matter first was confusing; second, was not promulgated in accordance with rulemaking requirements; and third, was not enforced.

In fact HCFA recognized the confusion and implemented regulations in 1995 which brought clarity to this issue once and for all. These devices are now covered and paid for in nearly 95 percent of the cases.

Clearly, we are not the only provider who has had questions about Medicare's payment guidelines regarding investigational devices. My staff followed our counsel's advice; if, after the fact, HCFA or Congress desires to provide further clarification about payment issues, we are eager to understand it and to resolve any question of overpayment in a fair and equitable fashion. Thank you.

[The prepared statement of Mr. Sanzo follows:]

PREPARED STATEMENT OF ANTHONY M. SANZO

My name is Anthony Sanzo. I am President and Chief Executive Officer of Allegheny General Hospital in Pittsburgh, Pennsylvania. I welcome the opportunity to come before the Subcommittee to help clarify Medicare reimbursement issues involving the use of investigational devices to treat Medicare beneficiaries.

As you know, this issue has long been surrounded by confusion and uncertainty—indeed, since the Medicare prospective payment system was established in 1983. During that time, health care providers have lacked a clear set of rules defining reimbursement for the treatment of Medicare beneficiaries when investigational devices are involved in the course of that treatment. It was not until 1995 that providers received clear guidance by regulations promulgated by HCFA.

I would like to take this opportunity to briefly outline the points that I believe are important to this discussion. Let me make just five points:

First, Allegheny has a history and commitment to advancing clinical knowledge. We are proud participants in the FDA-approved clinical trials in question. Through our participation in the clinical studies, we were able to provide our patients with new technologies that were obviously and compellingly superior to existing devices. In fact, it was our desire to provide superior care to our patients that dictated the use of the investigational devices in question. In the course of evaluating patients with life threatening illnesses, it occasionally became apparent that a patient would materially benefit from receiving such an investigational device. To not use clearly superior investigational devices when warranted clinically would be unethical. Specifically withholding these devices from Medicare patients would be discriminatory and reprehensible.

Second, the use of the term "investigational" to label these devices must be placed in context. All devices were approved for use in human beings and sold or given to hospitals for use under the auspices of FDA-approved clinical trials. In almost all cases, the "investigational" devices were new generations of existing technologies and incorporated improved design and technology.

Third, since 1983, Medicare has been paying hospitals a prospectively-established case payment for inpatient care regardless of the cost incurred by the hospital in providing that care. Therefore, Allegheny's payment for services involving the use of the devices under FDA-approved clinical trials was the same as our payment would have been if we had implanted the clinically-inferior devices previously approved by the FDA.

Fourth, Allegheny made a good faith effort to understand and to comply with HCFA guidelines regarding reimbursement for investigational devices. Approximately 130 of the finest medical centers in the country find themselves in the same situation. This is not an Allegheny-specific issue.

Finally, HCFA's policy on this matter (1) was confusing; (2) was not promulgated in accordance with rulemaking requirements; and (3) was not enforced. In fact, HCFA recognized the confusion and implemented regulations in 1995 which brought clarity to this issue once and for all. These devices are now covered and paid for.

Clearly, we are not the only provider who has had questions about Medicare's payment guidelines regarding investigational devices. My staff followed our counsel's advice; if, after the fact, HCFA or Congress desires to provide further clarification about payment issues, we are eager to understand it and resolve any question over payment in a fair and equitable fashion.

Chairman ROTH. Thank you, Mr. Sanzo.

Gentlemen, our investigation has revealed that each of your hospitals did have evidence in its files indicating that Medicare would not pay for investigational devices and related procedures. Yet, notwithstanding this, your hospitals each billed and received reimbursement from Medicare for these devices and procedures.

I would like to begin with Sutter Memorial Hospital if I may. Mr. Fry, I want to show you a November 5, 1991, letter from a Medicare auditor in which Sutter Memorial Hospital was formally notified that Medicare would not pay for a procedure in which an experimental pacemaker was implanted in the patient.[1]

I quote from that letter: "This is an experimental procedure and not covered by the Medicare program." The hospital subsequently continued to bill Medicare on numerous occasions for investigational device and procedures and received millions of dollars from Medicare.

Mr. Fry, is that not true?

Mr. FRY. Senator, this is the first time that I have ever seen this document and recall that I did not even assume my position at Sutter Memorial Hospital until late December of 1993.

Chairman ROTH. Who at Sutter Memorial Hospital would have made the decision to continue to bill Medicare for these investigational devices and procedures after the hospital did have knowledge of the fact that Medicare would not pay?

Mr. FRY. Senator, I am not aware of who was involved in this particular issue because I was not there at the time.

Chairman ROTH. Let me show you what I consider a very troublesome document. It is an April 13, 1994, memo from you, Mr. Rieger, to Mr. Fry.[2]

Mr. Rieger, you wrote this memo in response to a request from Mr. Fry, is that correct?

Mr. RIEGER. That is correct.

Chairman ROTH. And Mr. Fry, what prompted you to ask Mr. Rieger to look into this issue?

Mr. FRY. As I stated in my testimony earlier, that I had received a phone call from a cardiac surgeon inquiring to what Sutter Memorial Hospital's practices were with respect to investigational devices.

Chairman ROTH. Who was that?

Mr. FRY. That was a cardiac surgeon by the name of Dr. George Miller.

Chairman ROTH. Did not Dr. Miller specifically ask you whether Sutter Memorial Hospital was getting paid for procedures involving investigational devices?

Mr. FRY. That was part of his question to me, yes.

Chairman ROTH. Dr. Miller was not an employee of your hospital when he asked this question, was he?

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[1] The document was marked Exhibit No. 12 and can be found on page 98.
[2] The document was marked Exhibit No. 15 and can be found on page 106.

Mr. FRY. No, he was not.

Chairman ROTH. In fact, is he not a consultant for a medical device company?

Mr. FRY. I believe that Dr. Miller does work for, as an independent contractor for a company, yes.

Chairman ROTH. Mr. Rieger, how many documents did you attach to this memorandum?

Mr. RIEGER. One document.[1]

Chairman ROTH. Mr. Rieger, does this memo accurately reflect what you learned during the course of your inquiry?

Mr. RIEGER. This inquiry was based on a very brief conversation that I had with a manager of the cath lab and a medical director for the organization, as well as a review of a legal opinion.

Chairman ROTH. Again, I would like a yes or no answer, does it reflect what you learned?

Mr. RIEGER. Yes. It reflects a summary of my review of those things.

Chairman ROTH. What did you learn?

Mr. RIEGER. Well, as I begin in my memo, I learned that there was a conundrum on the community regarding the reimbursement for investigational devices. It seemed that although Medicare may have a policy stating that hospitals were not to reimbursement for placing investigational devices, clearly the practice in the community was quite the opposite and that that practice had been going on for some time. And my intent with the memo was to indicate that we needed to look into this issue and try to bring some more clarity to it for the institution.

Chairman ROTH. I just read that one sentence, Medicare clearly does not reimbursement for non-FDA approved and/or investigational devices. You go on to state that in order to avoid denial by Medicare, patient consent forms that would clearly identify the device as investigational were not being kept in patient charts. That way a Medicare auditor would not discover that an investigational device had been used.

Mr. Rieger or Mr. Fry, is it not true that patient consent forms were, in fact, removed from the patient files?

Mr. FRY. No, that is not the case. In fact, the memo specifically says that the consents were kept in separate locations. To my knowledge I am not aware of any consents that were subsequently removed from the charts. And, in fact, post-OIG subpoena, we had an opportunity to review this issue at length and did find out that over 50 percent of the consents were, indeed, in the charts.

Mr. DAMELIN. Mr. Fry, if I may, did an internal review at the hospital conducted after you had received the IG subpoena reveal that, in fact, patient consent forms had been removed from some patient files?

Mr. FRY. To the best of my knowledge, the internal review identified that there was inconsistent practice in following the hospital's policy which was to keep the consents on the record.

Mr. DAMELIN. Were they, in fact, in some cases not kept in the patient record?

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[1] The document was marked Exhibit No. 25 and can be found on page 110.

Mr. FRY. That is correct, in less than 50 percent of the cases there were not consents on the record, which was contrary to hospital policy.

Mr. DAMELIN. So Mr. Fry, then, the representation in Mr. Rieger's memo is correct that patient consent forms in some cases were not being kept in the files, is that correct?

Mr. FRY. Mr. Rieger's memo states that consents were kept separately and if you read the next sentence it says, the consents are kept with SIMR. SIMR is an acronym for the Sutter Institute of Medical Research which oversees some of the research that we do. So, you know, and there are consents, investigational consents kept there also.

Mr. DAMELIN. That is a separate location from the patient file, is it not?

Mr. FRY. The SIMR is separate, yes.

Chairman ROTH. Mr. Fry, did you take any action to ensure that Sutter Memorial Hospital would not continue to bill Medicare for procedures using investigational devices?

Mr. FRY. Senator, after I had an opportunity to review this very briefly, the last part of Mr. Rieger's memo indicates that he is going to continue to do further research and, yes, we were waiting for further research to be done.

Chairman ROTH. Mr. Rieger, you go on to state: "That clearly by the letter of the law we are at risk, however, there is obviously no communication between FDA and HCFA which would easily allow HCFA to identify the devices. I would think our overall risks are small."

Are you not saying that while you realize your hospital was violating the law by billing Medicare, you probably were not going to get caught?

Mr. RIEGER. I think what I tried to say in the memo was that there was an inconsistency in the community between what hospitals were interpreting as the Medicare regulations and I think I overstate the Medicare policy at the time by suggesting that it was a law when, in fact, at that time, I believe it was a——

Chairman ROTH. Let me repeat my question. I would like a yes or no answer. Are you not saying that while you realize Sutter Memorial Hospital was violating the law by billing Medicare that the hospital probably was not going to get caught? Is that not really what you were saying?

Mr. RIEGER. What I was saying was that the risk for denial on that procedure was small.

Chairman ROTH. I would like a yes or no answer.

Mr. RIEGER. No, I do not believe that is what I meant by that.

Chairman ROTH. Mr. Fry, even after the date of Mr. Rieger's memo, Sutter Memorial Hospital did continue to seek reimbursement from Medicare for these procedures, is that correct?

Mr. FRY. Senator, after the memorandum was written and subsequent to the OIG subpoena there were three procedures that were performed in the facility and, in fact, in all three cases, we did give explicit instructions not to bill the Medicare program for those particular procedures. And I could share with you some of the detail on that if you would like.

Chairman ROTH. I do not believe time will permit it at this stage. But let me ask you this. Let me show you a UB–92 billing form sent to Medicare seeking payment for procedures involving an investigational device which took place in August 1994.[1]

Not only was this well after Mr. Rieger's memo, but it was after Sutter Memorial Hospital had received a subpoena for all documents relating to these billings.

Let me ask you this question, Mr. Fry, did Sutter Memorial Hospital ever make an effort to stop billing Medicare for these devices and related procedures?

Mr. FRY. Absolutely. I gave explicit instruction not to have the Medicare program billed for these procedures. And if you would permit, Senator, in one of the cases that was accidentally billed after the OIG subpoena, in fact, I was asked whether or not the hospital should allow the procedure to take place. And I did authorize that but I authorized it with the clear understanding that it would not be billed.

This patient was transported from another hospital in a life-threatening situation and the procedures that we had to ensure that the Medicare program would not be reimbursement were in the cath lab. This particular device was installed in the surgery room and it was outside of the process that we had set up and it was accidentally billed and we did subsequently reimburse the government for that.

Chairman ROTH. Mr. Stillman, I would now like to turn to you.

I would like you to look at two memos dated January 25, 1990 from your director of admitting. One is to you and one is to a group of three doctors. In the memo to you, the director of admitting states: "Due to the investigational nature of this device, it is considered a non-covered service by Medicare. Therefore, we should not be billing Medicare."

In the doctors' memo, the director of admitting states: "Our knowledge that the PCD implants are considered a non-covered service by Medicare will prohibit the medical center . . . from billing Medicare for any future admissions."[2]

Now, despite these very clear statements by the medical center's director of admitting, is it not true that the University of Washington Medical Center continued to bill Medicare for at least 135 patients who received investigational devices?

Mr. STILLMAN. Mr. Chairman, let me tell you why we did that.

Chairman ROTH. Please answer my question first, is that not accurate? Did you not continue to bill for those?

Mr. STILLMAN. And I would like to explain why we did that.

Chairman ROTH. But I am asking you for a yes or no answer and then we will give you the chance to explain.

Mr. STILLMAN. We submitted claims for implantation of cardiac devices.

Chairman ROTH. The answer is yes?

Mr. STILLMAN. Yes.

Chairman ROTH. All right.

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[1] The document was marked Exhibit No. 16 and is retained in the files of the Subcommittee.
[2] The documents were marked Exhibit No. 5 and 6 and can be found on pages 90 and 91.

Mr. STILLMAN. And let me explain why we did that. Basically my experience in health care administration and management is that all payors, including the Medicare program, are primarily directed by medical necessity and that is the driving force in what is covered and what will be paid for.

All payors, underlying that, have biases, policies that deal with payments and a lot of those are biases in favor of not paying. But my experience is that medical necessity overrides those biases to not pay and so what we need to do is to get into a process of justifying the medical necessity of the treatment that we are pursuing.

What we did with a number of payors was engage in getting pre-authorization from those payors to provide those services. And discuss with them in advance, clinician-to-clinician, nurse/doctor-to-medical director of those payors, what the medical necessity of those treatments were and get pre-authorization for those.

The Medicare program, as I stated in my statement, refused to grant those pre-authorizations and required that we submit a claim for the services and they would engage in retrospective review.

We made full and complete disclosure in our records of the device that we were using and the necessity of those devices. The result of that was in a number of cases the Medicare program specifically audited our claims, specifically looked at our medical records, our billing documents, with a notice from them, when they came out to do the review that this may be excluded from Medicare coverage.

I mean that was specifically on that directive, looking specifically at these devices. They specifically reviewed those and every one of those that they reviewed they found that the service was medically necessary and approved the payment of those claims.

The second result was that the Medicare program paid no more than it would have paid using the AICD device which was the one that was the predecessor device that I addressed in my statement with the clinical risk.

Finally, we were able to provide to our patients the best quality care that was available in a way that was judged medically necessary not only by my own clinicians but also by the Medicare audit.

Chairman ROTH. If I may continue, let me show you a memo dated April 26, 1990, from Dr. Gust Bardy, a cardiac surgeon employed by the University of Washington Medical Center. In this memo, Dr. Bardy notes, and I quote: "One small but I believe important point is to call all these units 'Implantable Defibrillator Systems.' This is a more generic term than AICD or PCD and will avoid setting flags over the letters PCD."

Now, on this memo, you handwrote the notation, I quote again: "Are we covering something up here?" What were you concerned about covering up? [1]

Mr. STILLMAN. When I received this memo—and I don't know where I got this memo, but that is clearly my handwriting. When I received the memo, I said, you know, what is going on? He is saying things setting flags. I would naturally be responsive to that.

[1] The document was marked Exhibit No. 8 and can be found on page 94

What I needed to be assured of, and what I was assured of, was that we weren't covering anything up, and the institution would not tolerate that and I would not accept that.

I would like to read some information that was covered up in this overhead. It is part of the complete memo. If I can just read this whole paragraph.

Chairman ROTH. Please proceed.

Mr. STILLMAN. OK. "In order to standardize the approval process, my nurse, Charlie Troutman"—and this is from Dr. Bardy to me, or to Eric Larsen—"will process the authorization for implantation of the defibrillator systems with third-party payers (Medicare, Medicaid, Group Health, and private insurers). After this authorization is received, it will be forwarded to Kim Baird or Andrea DeCano to be distributed to Financial Services (Becky Mounce and Lynn Poser) and Nancy Irvin. The intention is to decrease the redundancy of effort and to avoid conflicts about reimbursement for implantable defibrillator systems. The more people involved, the more difficult it becomes to get third party reimbursement."

What we were trying to do is get it so that we have the clinicians providing the information, getting the pre-authorizations, hopefully, at this time, pre-authorizations from payors before we provide this service. We are aiming to get full and complete disclosure. We are aiming to provide supplemental information, have contacts with the payors specifically.

I want to reinforce I would not have been satisfied until I knew that there would have been full and complete disclosure of this information and that we were, indeed, not trying to cover anything up. And I know the institution's position at that time and now would be exactly the same.

Mr. DAMELIN. Mr. Stillman, there is a comment towards the bottom of that document: "If not FDA approved-can't bill. It's against Medicare/Medicaid regs." Did you write that?

Mr. STILLMAN. I did not write that.

Mr. DAMELIN. Do you know who did?

Mr. STILLMAN. I don't know who wrote that. I don't recognize the handwriting. I don't agree with the statement and would not have agreed at that time.

Chairman ROTH. What did you do to follow up your concerns about a possible coverup?

Mr. STILLMAN. Another copy of this that I have looked at in preparing for meetings with Mr. Damelin and his staff and in this testimony was that this was received by Eric Larsen. I was cc'd. He made a note to send a copy to me. When Eric Larsen, who is the Medical Director of the institution, copies me on things, calls me up about things, I get back with him and discuss that. I would have been certain that I would have gotten back with Dr. Larsen, discussed this issue. I am sure that this would have been his same concern that we weren't covering anything up.

But I would read my comment as making sure that we were not, indeed, covering anything up here and actually were making full and complete disclosure.

Chairman ROTH. Let me show you another memo from Dr. Bardy, this one dated April 30, 1990, where he tells you that the medical center shouldn't have trouble getting reimbursed from

Medicare "as long as attention isn't drawn to the investigational nature of the PCD." [1]

How did you interpret Dr. Bardy's comment, especially in light of your notation 4 days earlier on the previous memo regarding a possible coverup?

Mr. STILLMAN. I would like to also read the portion of the document that is covered up by this enlargement. So just before "this has proven satisfactory" is an "after chart review by the third-party"——

Chairman ROTH. That is fine, but before you read that, I would like you to answer my question. How did you interpret Dr. Bardy's comment?

Mr. STILLMAN. Part of what I am going to read was in the balance of this note and it flavors what I would have been thinking when I read this. So I think it is very pertinent to how I responded.

"Payment for Implantable Defibrillator Systems with insurers that don't grant preauthorization usually follows chart review by the third party payers. We facilitate this retrospective approval process,"—and that is what Medicare was following—"in the case of Medicare, by inserting a letter in the chart justifying defibrillator insertion. In the case of Pierce County, etc., we typically fax a letter to them."

So what we are doing is we are supplementing the information that was already in the chart describing the treatment we were providing, the devices we were using. All of that is still in there, and we are adding to that, in fact, enhancing disclosure about why this is medically necessary, and to give full disclosure, we certainly were not putting anything behind the scenes. This was really to enhance it.

And so I would have been confident——

Chairman ROTH. It is difficult to understand this language, "and should be the same for our PCD patients as long as attention isn't drawn to the investigational nature of the PCD."

Let me go ahead. Mr. Stillman, Dr. Bardy is a State employee, isn't he?

Mr. STILLMAN. He is a faculty member at the University of Washington and is a professor in the University of Washington.

Chairman ROTH. When Dr. Bardy wrote the two memos, he was also being paid by the device manufacturer, wasn't he?

Mr. STILLMAN. My understanding is he had a grant relationship with the manufacturer. I don't know—the medical school side and the faculty compensation is not something that I am responsible for, nor privy to.

Chairman ROTH. Was Dr. Bardy ordered by the University of Washington recently to sever his financial relationship with the manufacturer?

Mr. STILLMAN. What I know about the relationship is that his relationship is under review and that is ongoing at this time.

Chairman ROTH. It appears that the medical center continued to seek payment from Medicare despite having received a letter from Blue Cross, the Medicare intermediary, that clearly states Medicare would not pay for any procedures relating to the implantation

[1] The document was marked Exhibit No. 10 and can be found on page 96.

of an investigational PCD device. Let me show you a September 4, 1990, letter your billing department received from Blue Cross, which states: "Program payment . . . may not be made for medical procedures using such devices. . . . Until such time as it has . . . been FDA approved, it does not appear that the program can make any payment when a PCD is implanted." [1]

With this letter in hand, did the university continue to seek reimbursement from Medicare? Again, I would ask you to answer yes or no.

Mr. STILLMAN. And will I then have a chance to explain?

Chairman ROTH. Yes, of course.

Mr. STILLMAN. After this date, September 4, 1990, we did submit claims to the Medicare program for this. What I would like in addition to say is, again, part of the document was covered up with this enlargement, and that was that in reviewing the hospital manual, I came across a reference which I believe addresses this question. And so it is referencing a hospital manual which is a policy interpretation. It is as I described before, that the bias or the policies are set up to not pay, and so this is restating what I already said was that payors, including the Medicare program, have biases and policies not to pay, and that is what the hospital manual would be, directions from HCFA to intermediaries on how they want to carry out things.

Mr. DAMELIN. Mr. Stillman, the University of Washington had requested this interpretation, did they not? Because the first sentence states——

Mr. STILLMAN. Yes, "I am writing in response. . . ."

Mr. DAMELIN. "I am writing in response to your August 1 letter requesting clarification of Medicare coverage for patients admitted for implantation of a Pacemaker Cardioverter Defibrillator which, as you state in your letter is still in clinical trials." So this letter was given to the University of Washington in response to a request; correct?

Mr. STILLMAN. That is what this says. I did not receive this letter and do not recall having seen this before I started preparing for these meetings.

Chairman ROTH. Well, thank you, Mr. Stillman.

We will now turn to you, Mr. Sanzo. First let me show you a chart which was produced by Allegheny General Hospital in response to the HHS IG subpoena which reflects Medicare and Medicaid billings between July 5, 1988, and September 30, 1993, for procedures in which investigational devices were used. Isn't it correct that each entry on this chart represents an effort to receive payment from Medicare for procedures involving investigational devices? [2]

Mr. SANZO. Yes.

Chairman ROTH. Now let me show you a memo prepared by the hospital director of reimbursement dated July 7, 1989, in which it is stated that the hospital had been "formally or finally notified that Medicare/Blue Cross will not cover the entire patient stay

[1] The document was marked Exhibit No. 11 and can be found on page 97.
[2] The document was marked Exhibit No. 18 and can be found on page 107.

when admission is for the insertion of a non-FDA-approved pacemaker. Medicaid will also deny this stay." [1]

In light of this information, how did Allegheny General Hospital reach the conclusion that it could bill Medicare for procedures involving investigational devices?

Mr. SANZO. This memorandum raised questions in my staff's mind about our ability to get paid by Medicare, and what happened subsequent to this memorandum was that the billing for the investigative studies was suspended until further clarification was obtained. Our organization then sought further clarification through the intermediary and also from the advice of counsel. Once having clarification sufficient to enable us to make a final conclusion, we then restarted the billing process sometime after this.

Chairman ROTH. Let me show you another memo from the director of reimbursement dated August 18, 1989, which discusses the fact that Allegheny had been paid by Medicare for procedures involving the implantation of experimental pacemakers. In attempting to explain how payment was approved, the director of reimbursement stated that, and I quote: "I would guess they have been approved because a pacer was billed with no notation of what pacer was used." [2]

Doesn't this seem to indicate that Allegheny was attempting to mislead Medicare?

Mr. SANZO. No, sir, not to me. And perhaps not to me because I know that Allegheny made full and complete disclosure of the use of all investigational devices within the patient's medical record. That full disclosure included, at minimum, a signed consent, and often included the stapled label of the investigational device into the medical record. Those charts were made available on request to the peer review organization which, as you know, is an agent of Medicare doing reviews on Medicare's behalf. And in all cases, the peer review organization understood that we were involved in the clinical trial, did not change the DRG designation noted, and did not recommend or deny payment for the care rendered.

Chairman ROTH. Subsequent to the August 18, 1989 memo, did the hospital ever disclose to Medicare that any of its bills reflected procedures involving investigational devices?

Mr. SANZO. Through the medical records, sir, yes.

Chairman ROTH. The what?

Mr. SANZO. Through the medical records, sir, yes.

Chairman ROTH. Was there any indication on the bills that were submitted?

Mr. SANZO. No, sir. My understanding is that in a document that had been circulated by Mr. Ault to all of the regional administrators, dated December 28, 1994—and I am quoting: "The current inpatient hospital claim form, HCFA 1450, does not call for the information necessary for identifying the type of medical device used or billed for. Focused medical review is needed to determine what type of device is used and whether it is FDA approved for investigational," and for that reason we made sure that that notation was clear and evident within the medical record.

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[1] The document was marked Exhibit No. 1 and can be found on page 83.
[2] The document was marked Exhibit No. 2 and can be found on page 86.

Chairman ROTH. Let me show you a memo dated October 24, 1989, in which the administrative director of the Cardiology Department seeks permission to bill Medicare for procedures involving the implantation of investigational devices. Didn't Allegheny General Hospital decide to bill Medicare in response to this request? [1]

Mr. SANZO. This document dated October 24th followed the further clarification that was sought and our advice from counsel, and subsequent to this period of time, yes, in fact, we resumed billing.

Chairman ROTH. Wasn't this decision totally contrary to the information contained in the July 7, 1989, memo I showed you previously, as well as the November 6, 1989, memo which I show you now where the director of reimbursement states that: "We were informed by Medicare/Blue Cross that a patient's entire stay would be denied if an investigational/experimental pacer was implanted"?

Mr. SANZO. Sir, I am looking at both of those documents, and the questions that were raised by my staff after reading the July 7, 1989, memorandum revolve around a couple of issues. The first is that this says the "entire patient stay would not be paid," leaving open the question that a partial stay might be paid. And, second, it says when the admission is for the insertion of a non-FDA-approved pacemaker, again raising the question of an admission for the evaluation of an arrhythmia and a subsequent determination that a pacemaker would be the best way to treat that patient.

Chairman ROTH. You are saying that because they use the word "entire," maybe a partial stay would be paid. Did you go back and seek a clarification on that point?

Mr. SANZO. In fact, in March of 1990, we received information from the intermediary that makes two things obvious. The first is that it is possible that we would be paid for a partial portion of the stay. And, second, we were advised to review this with Keypro, the peer review organization to which I previously referred.

Chairman ROTH. Yes. Would you submit a copy of that?

Mr. SANZO. Yes, sir. We certainly will do so again. It is March 19, 1990.[2]

Chairman ROTH. Mr. Sanzo, all or portions of certain memos requested by the Subcommittee have been withheld based on a claim of attorney-client privilege. Was your hospital's decision to go forward and bill Medicare for procedures involving investigational devices based on advice of counsel?

Mr. SANZO. Senator, I cannot divulge that advice at this time, and as you know——

Chairman ROTH. You can't say who gave this advice? Was it counsel?

Mr. SANZO. The review included in part review from counsel, yes, sir, but I am not at all at this time willing to decline or waive our privilege for client-attorney confidentiality.

Chairman ROTH. Was the advice in the form of a written opinion?

Mr. SANZO. My understanding, sir, is that the advice came in an oral form, but my claim of withholding that advice at this point in

[1] The document was marked Exhibit No. 3 and can be found on page 88.
[2] The document was marked Exhibit No. 7 and can be found on page 93.

time is because even if I tell you what the oral advice was, I would be waiving my attorney-client privilege, which I respectfully decline to do at this point in time.

Chairman ROTH. It would not be waiving it to give the name of the attorney who gave you that advice, would it?

Mr. SANZO. It would not, sir.

Chairman ROTH. Who was the attorney?

Mr. SANZO. Mr. Chris Copeland, sir.

Mr. DAMELIN. Mr. Sanzo, just to clarify, if I may, you had made reference to a March 1990 clarification in connection with a Medicare intermediary; is that right?

Mr. SANZO. Yes, sir.

Mr. DAMELIN. Was that a written communication or was that an oral conversation that was put into writing by a member of your staff?

Mr. SANZO. I am not aware whether it came orally or in writing, just as I am not aware of the prior notice from the intermediary coming orally or in writing.

Mr. DAMELIN. The document you have just given us states, "This morning I spoke with Brian Teagarden in regard to two protocols which were submitted to him. He gave me the following information for Blue Cross and Medicare reimbursement." That reflects a telephone conversation. Was there anything ever submitted in writing as a result of that?

Mr. SANZO. I honestly don't know the answer to that question, sir.

Mr. DAMELIN. In the course of that memo where it is referenced under number two, Medicare—do you see item number two, Medicare?

Mr. SANZO. Yes, sir.

Mr. DAMELIN. OK. In the second paragraph down?

Mr. SANZO. Yes, sir.

Mr. DAMELIN. It states that, "In his opinion, if the patient is admitted solely for the TEC procedure, which is investigational, the reimbursement would be denied." Is that correct?

Mr. SANZO. That is correct.

Mr. DAMELIN. So if somebody was admitted—based on that advice, Mr. Sanzo, if somebody was admitted into Allegheny Hospital solely for the implantation of an experimental or investigational device, based on that advice that you got in March 1990, would the claim be denied?

Mr. SANZO. I think so, sir, based on that advice.

Mr. DAMELIN. So when somebody is admitted to the hospital solely for the implantation of an investigational device, Medicare is telling you the claim would be denied; correct?

Mr. SANZO. It appears so, sir, yes.

Mr. DAMELIN. Do you know if after March 1990 the hospital ever billed Medicare for procedures involving the implantation of experimental or investigational devices?

Mr. SANZO. We did bill for services rendered with an investigational device. I am not aware if we billed if the patient was specifically admitted for use of investigational devices.

Mr. DAMELIN. It was just that purpose?

Mr. SANZO. Yes, I am not aware——

Mr. DAMELIN. You don't know, do you?

Mr. SANZO. I do not know, sir.

Mr. DAMELIN. Thank you.

Chairman ROTH. Gentlemen, those are all the questions we have at the present time. We will leave the record open for a period of 30 days for additional material to be submitted for the record.

We will include as if read a statement by the ranking member, Senator Nunn and also a statement from Senator Cohen.

[The prepared statements of Senator Nunn and Cohen follow:]

OPENING STATEMENT OF SENATOR SAM NUNN

When the art of medicine becomes the business of medicine, it demands not only medical ethics but business ethics as well. Unfortunately, such ethics often seem to be lacking—particularly when it comes to those providers who service the Medicare population. Whether it be billing Medicare vastly inflated prices for services and supplies, billing for services never rendered, or manipulating procedure codes in order to bill more than appropriate, the abuses seem never-ending. As a result, our Medicare program costs keep going up and up and up—to the point where we are spending over 14 percent of our Federal budget on Medicare.

Today's hearing, which will focus on hospitals billing Medicare for investigational devices in contravention of Medicare policy, is in my opinion yet one more example of how those who have turned medicine into a business are in need of a lesson in ethics. There are those who will say that this hearing is unnecessary—that the policy on billing Medicare for investigational devices was unclear, was improperly promulgated, and, in any event, has been subsequently reversed. They say the issue is not about hospitals billing Medicare for these devices, but about hospitals providing their patients with the latest and best in medical technology.

From where I sit, I find it odd that these arguments were never made during the nine or so years that this policy was in place, but only after investigations found widespread abuse of the policy. And from what I have seen of the cases before the Subcommittee today, I see this not so much as an issue of hospitals and doctors looking out for their patients, as an issue of hospitals and doctors looking out for the bottom line. Someone has to pay—and what easier target is there than Medicare? So what if billing for such devices violates Medicare policy? These are the words of one of the hospitals from which we will hear today:

> Some of these devices will become FDA approved by the time we could potentially be audited. Clearly, by the letter of the law we are at risk. However, there is obviously no communication between FDA and HCFA which would easily allow HCFA to identify the devices and given the large number of exemptions currently occurring, I would think our overall risks are small.

The evidence before the Subcommittee today shows that many of the hospitals which engaged in this activity were very clear as to what the Medicare policy was—they simply chose to ignore it. Moreover, the evidence also shows that for many hospitals and doctors, the motivation for ignoring this policy was clearly a matter of business. The same hospital that weighed the risks of being caught improperly billing Medicare for investigational devices discussed the doctors who were implanting these devices in the following terms:

> Dr.'s Sharma and O'Neil are very active in using investigational devices. . . . Their business is important to the lab here and to halt this activity would clearly drive their business elsewhere.

Much has been made of the fact that Medicare's policy on paying for these devices has, as of the end of last year, been changed to now permit payment. I find this totally irrelevant to the issue before us. Congress recently passed legislation allowing States to raise their speed limits above 55 miles per hour. Yet no one would argue that this legislation means that one who was caught speeding 3 years ago is now no longer guilty. We are all bound to obey the law as it exists at the time of our actions. what the Subcommittee is examining today are actions which violated Medicare policy as it existed at the time those actions were taken.

If one needs any more proof that this is an issue of ethics, of abuse, and of right and wrong, one need only look at the example of Farrell Maier, who will appear later this morning. Mr. Maier was the Director of the Business Office of the Baptist Medical Center in Oklahoma City. Despite pressure from doctors at his institution,

and despite being told that other hospitals were billing for investigational devices, Mr. Maier refused to bill Medicare for these devices because he knew it was against Medicare policy. In the words of Mr. Maier, "The integrity of the entire system depends on the integrity of every individual within the system."

I applaud Mr. Maier, as I applaud the hundreds of doctors and hospitals nationwide who have complied with the system throughout the years. Unfortunately, the actions of a few not only can tarnish the good work of many, but can also endanger the integrity and the viability of the system in which all must work. It is for that reason that I also applaud Senator Roth for pursuing this issue and for his efforts to protect the integrity and the viability of our Medicare system. I look forward to today's hearing and I look forward to continuing to work with the Chairman and my other colleagues to root out those abuses which undermine our confidence in today's institutions.

PREPARED STATEMENT OF SENATOR WILLIAM S. COHEN

Mr. Chairman, I want to commend you for holding this important hearing today on allegations of improper medical billings by hospitals for investigational devices and procedures. As the author of the health care anti-fraud and abuse legislation that is contained in the balanced budget reconciliation conference agreement, I believe it is crucial that we do all we can to identify and crack down on the fraud that pervades Medicare. I would also like to take this opportunity to thank you for all of your support and leadership in assuring that these important provisions remained intact during the conference negotiations late last year. Your continuing commitment on this important issue demonstrates your dedication to uncovering and fixing problems that plague our Medicare and Medicaid programs.

Mr. Chairman, the allegations made by the first witness today and outlined in the testimony of the HHS' Inspector General are yet another example of fraud that is infiltrating our health care system and driving Medicare further down the road to bankruptcy.

As Chairman of the Special Committee on Aging, one of my top priorities has been to improve the Federal Government's response to health care fraud. Estimates are that we are losing as much as $100 billion each year to health care fraud, with Medicare and other Federal health care programs picking up the tab for as much as $40 billion of this fraud.

The Aging Committee has held several hearings on health care fraud schemes ranging from nursing home abuses and home care fraud to so-called "professional patients" who work with fraudulent providers or middlemen to rip-off health care programs. At one of our hearings, we heard disturbing testimony from FBI Director Louis Freeh that health care fraud is one of the biggest challenges facing law enforcement, and that even drug dealers are moving into health care fraud because, as Willie Sutton would say, "That's where the money is."

I am pleased that both the Senate and House have passed legislation to toughen our defenses against health care fraud. The budget reconciliation bill passed last fall includes provisions I introduced to create a Federal health care fraud statute, toughen criminal and civil monetary penalties against health care fraud, and better coordinate Federal and State law enforcement efforts to fight this fraud.

Most importantly, this effort will provide the most important tools necessary to combat fraud effectively: more investigators and more resources. We now have a situation where the mouse is outsmarting the mousetrap and we have far too few resources devoted to anti-health care fraud efforts. Our legislation would establish an account through which health care fraud enforcement efforts would be funded each year.

The proposal that passed is a tough, yet reasonable and fair response to health care fraud, and has been supported by many health care groups that are working with Congress to rid the system of bad actors. Unfortunately, this legislation has been stalled as part of the budget breakdown. I think that this hearing once again illustrates how much we are losing each day to health care fraud and abuse and how we must do all we can to stop health care fraud from bleeding billions of dollars from Medicare and Medicaid.

Mr. Chairman, I would like to make a few observations about today's hearing.

First, we must be careful not to criticize all teaching hospitals who hold clinical trials to test experimental devices or procedures or all manufacturers of investigational devices. If allegations of intentional false billing or misrepresentations to Medicare are true, we should take swift and immediate action to crack down and penalize the fraudulent actors. We should do all we can to identify the extent of the fraud, but the actions of some bad actors should not cast aspersion on an entire in-

dustry which labors to provide innovative products and services to individuals who may be in need of the latest technologies.

Nevertheless, the Subcommittee's investigation has uncovered very disturbing evidence suggesting that several teaching hospitals knowingly billed Medicare for certain cardiac devices that they knew that Medicare did not pay for—and that some hospitals took conscious steps to misrepresent the fact that these devices were investigational and not yet approved by the FDA.

Second, we should make it clear that the point of today's hearing is not whether Medicare should or should not pay for investigational devices. I believe we are in agreement that depriving patients of advanced treatments and of the benefits of new technologies is not appropriate. Investigational devices can provide potentially life-saving benefits to patients and are a crucial aspect of advancing our knowledge of medicine.

The real issue for the Subcommittee today is whether certain physicians and hospitals knowingly submitted claims for investigational cardiac devices which they knew were not covered by Medicare. Moreover, did certain physicians and/or hospitals then try to obfuscate the nature of these particular devices and procedures in the billings they submitted to Medicare and should we then exonerate such allegedly abusive and improper billings?

If a handful of hospitals did deliberately misrepresent their billings to Medicare, then HCFA should seek, at a minimum, to recoup these overcharges. In addition to the billing question, I am also concerned about whether some beneficiaries were unaware of the fact that the implanted devices had not yet been approved as safe and effective and whether the appropriate consent forms had been properly documented. These are questions which I believe the Subcommittee will address at today's hearing.

Although I am unable to attend today's hearing, I intend to follow up with the Chairman as he continues to pursue and investigate this area. Again, I want to thank the Chairman for his dedication and unyielding support for strong health care anti-fraud efforts.

Chairman ROTH. Mr. Stillman, as you heard me indicate earlier, you submitted a number of questions.

Mr. STILLMAN. That is correct.

Chairman ROTH. We will submit them for answers in writing and make certain that you receive a copy.[1] This is an unusual procedure, but we will proceed along those lines.

Mr. STILLMAN. Thank you. We appreciate that, Mr. Chairman.

Chairman ROTH. The Subcommittee is in recess.

[Whereupon, at 1:34 p.m., the Subcommittee was adjourned.]

[1] The documents referred to were marked Exhibits 29 and 31, and are retained in the files of the Subcommittee.

APPENDIX

AGH
LEGHENY GENERAL HOSPITAL

320 East North Avenue
Pittsburgh, Pennsylvania 15[illegible]
412-359-[illegible]

July 7, 1989

Assistant Vice President

TO: Dave Baranik
Director, Finance

FROM: Marjorie E. McNeil MEM
Director, Facility and Physician Reimbursement

SUBJECT: Non-FDA approved pacemakers

We have been formally or finally notified that Medicare/Blue Cross will not cover the entire patient stay when admission is for the insertion of a non-FDA approved pacemaker. Medicaid will also deny the stay. Attached are relevant sections from the HIM 10 provided by Brian Teegarden.

If additional information is required, please let me know.

MEM:jmk
M5:44

cc. Andrea Badway
Bob Katchur
John O'Brien
Connie Cibrone

Senate Permanent Subcommittee on Investigations
EXHIBIT # 1

MARGE MEMO

WC-H

RECEIVED JUL 07 1989

B. Devices Not Approved by FDA.--Medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures or services performed using devices which have not been approved for marketing by FDA.

260.2 No Legal Obligation to Pay for or Provide Services.--Program payment may not be made for items or services which neither the beneficiary nor any other person or organization has a legal obligation to pay for or provide. This exclusion applies where items and services are furnished gratuitously without regard to the beneficiary's ability to pay and without expectation of payment from any source, such as free X-rays or immunizations provided by health organizations. However, Medicare reimbursement is not precluded merely because a provider, physician, or supplier waives the charge in the case of a particular patient or a group or class of patients, as the waiver of charges for some patients does not impair the right to charge others, including Medicare patients. The determinative factor in applying this exclusion is the reason the particular individual is not charged.

The following sections illustrate the applicability of this exclusion to various situations involving services other than those paid for directly or indirectly by a governmental entity. (For a discussion of the latter, see § 260.3.)

A. Indigency.--This exclusion does not apply where items and services are furnished an indigent individual without charge because of his inability to pay, if the provider, physician, or supplier bills other patients to the extent that they are able to pay.

B. Provider, Physician, or Supplier Bills Only Insured Patients.--Some providers, physicians, and suppliers waive their charges for individuals of limited means, but they also expect to be paid where the patient has insurance which covers the items or services they furnish. In such a situation, because it is clear that a patient would be charged if insured, benefits are payable for services rendered to patients with medical insurance if the provider, physician, or supplier customarily bills all insured patients--not just Medicare patients--even though non-insured patients are not charged.

Individuals with conditions which are the subject of a research project may receive treatment financed by a private research foundation. The foundation may establish its own clinic to study certain diseases or it may make grants to various other organizations. In most cases, the patient is not expected to pay for his treatment out-of-pocket, but if he has insurance, the parties expect that the insurer will pay for the services. In this situation, a legal obligation is considered to exist in the case of a Medicare patient even though other patients may not have insurance and are not charged.

C. Medicare Patient has Other Health Insurance.--Except as provided in §§ 262ff., 263ff. and 264ff. payment is not precluded under Medicare even though the patient is covered by another health insurance plan or program which is obligated to provide or pay for the same services. This plan may be the type which pays money toward the cost of the services, such as a health insurance policy, or it may be the type which organizes and maintains its own facilities and professional staff. Examples of this latter type are employer and union sponsored plans which furnish services to special groups of employees or retirees or to union members, and group practice prepayment plans.

3101.14 Services Related to and Required as a Result of Services Which are Not Covered Under Medicare.--

A. Medical and hospital services are sometimes required to treat a condition that arises as a result of services which are not covered because they are determined to be not reasonable and necessary or because they are excluded from coverage for other reasons. Services "related to" noncovered services (e.g., cosmetic surgery, noncovered organ transplants, noncovered artificial organ implants, etc.), including services related to followup care and complications of noncovered services which require treatment during a hospital stay in which the noncovered service was performed, are not covered services under Medicare. Services "not related to" noncovered services are covered under Medicare. To the extent that you are responsible for making medical coverage decisions in such cases involving inpatient stays, follow the procedures established below.

B. Identify which services are related to noncovered services and which are not. Following are some examples of services "related to" and "not related to" noncovered services while the beneficiary is an inpatient:

1. A beneficiary was hospitalized for a noncovered service and broke a leg while in the hospital. Services related to care of the broken leg during this stay is a clear cut example of "not related to" services and are covered under Medicare.

2. A beneficiary was admitted to the hospital for covered services, but during the course of hospitalization became a candidate for a noncovered transplant or implant and actually received the transplant or implant during that hospital stay. When the original admission was entirely unrelated to the diagnosis that led to a recommendation for a noncovered transplant or implant, the services related to the admitting condition would be covered.

3. A beneficiary was admitted to the hospital for covered services related to a condition which ultimately led to identification of a need for transplant and receipt of a transplant during the same hospital stay. If, on the basis of the nature of the services and a comparison of the date they are received with the date on which the beneficiary is identified as a transplant candidate, the services could reasonably be attributed to preparation for the noncovered transplant, the services would be "related to" noncovered services and would also be noncovered.

C. After a beneficiary has been discharged from the hospital stay in which he received noncovered services, medical and hospital services required to treat a condition or complication that arises as a result of the prior noncovered services may be covered when they are reasonable and necessary in all other respects. Thus, coverage could be provided for subsequent inpatient stays or outpatient treatment ordinarily covered by Medicare, even if the need for treatment arose because of a previous noncovered procedure. Some examples of services that may be found to be covered under this policy are the reversal of intestinal bypass surgery for obesity, repair of complications from transsexual surgery or from cosmetic surgery, removal of a noncovered bladder stimulator, or treatment of an infection at the surgical site of a noncovered transplant that occurred following discharge from the hospital.

However, any subsequent services that could be expected to have been incorporated into a global fee (i.e., a single charge for a group of services) should be denied. Thus, where a patient undergoes cosmetic surgery and the treatment regimen calls for a series of postoperative visits to the surgeon for evaluating the patient's progress, these visits should be denied. (See § 3619.12 and Hospital Manual § 415.18 for billing procedures.)

AGH
LEGHENY GENERAL HOSPITAL

320 East North Avenue
Pittsburgh, Pennsylvania 15212-9986
412-359-3131

August 18, 1989

TO: Charles Rakaczky
Administrative Fellow

FROM: Marjorie McNeil MMcN
Director, Facility & Physician Reimbursement

SUBJECT: Experimental Pacemakers

At your request, attached is the charge information on the patients receiving experimental pacers. You will note that all have been approved/paid by the third parties. Those not noted with payments are pending and have not been denied. I would guess they have been approved because a "pacer" was billed with no notation of what pacer was used.

The average charge, excluding the obvious outlier Lloyd, is $67,686. At a cost to charge ratio of .48, this would make the average cost per case at $32,489.

If additional information is required, please let me know.

MEM:kms
M6:23

Attachment

cc: D. Baranik

Senate Permanent Subcommittee on Investigations
EXHIBIT # 2

LLEGHENY GENERAL HOSPITAL
LECTROPHYSIOLOGY-PATIENTS RECEIVING INVESTIGATIONAL DEVICES
17-Aug-89

PATIENT	ID NUMBER	CHARGES	PAYMENTS	PAYOR
		24,975.51	24,975.51	MC
		42,185.78	42,185.78	MC
		32,223.38	32,223.38	MC
		36,684.38	36,684.38	MC
		84,887.42	84,887.42	MC
		63,346.83	63,346.83	MC
[redacted]		[redacted]	[redacted]	[redacted]
		93,314.19	0.00	MC
		57,447.83	57,447.83	MC
		386,252.88	0.00	MC
		63,216.83	63,216.83	MC
		53,242.38	0.00	MA
		61,578.54	0.00	MC
[redacted]		[redacted]	[redacted]	[redacted]
		39,381.88	39,381.88	MC
		186,658.87	186,658.87	MC
[redacted]		[redacted]	[redacted]	[redacted]
		62,515.78	62,515.78	
		178,891.55	0.00	
		81,461.88	0.00	
TAL CHARGES		1,727,671.72	889,487.16	
ERAGE CHARGE		78,530.53		

Average charge
- excluding Lloyd $ 67,686

AGH
HENY GENERAL HOSPITAL
320 East North Avenue
Pittsburgh, Pennsylvania 15212-9986
412-359-3131

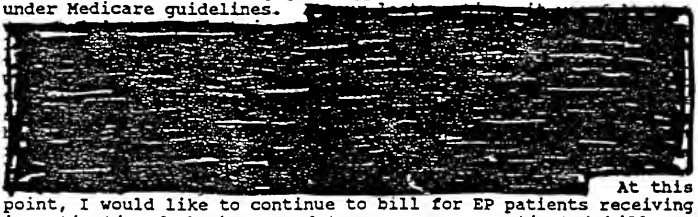
October 24, 1989

MEMO TO: Andrea Badway
Vice President

FROM: Charles J. Rakaczky
Administrative Director, Cardiology

SUBJECT: Electrophysiology Investigational Devices

As you are aware, the hospital has been trying to determine whether or not costs associated with implanting an investigational electrophysiology device could be reimbursed under Medicare guidelines.



At this point, I would like to continue to bill for EP patients receiving investigational devices, and to process any patients' bills we have held for processing until this determination has been finalized. I have sent Marj McNeil a memo to request her to continue billing for these patients. Please call me if you should have any questions.

Charles J. Rakaczky
Administrative Director, Cardiology

CJR:lap
epindev.ab

cc: Chris Copeland
Connie Cibrone
Fred M. Rankin III

Senate Permanent Subcommittee on Investigations
EXHIBIT # 3

AGH
HENY GENERAL HOSPITAL

320 East North Avenue
Pittsburgh, Pennsylvania 15212-9986
412-359-3131

To: Chris Copeland
✓ Fred Rankin

November 6, 1989

TO: Joseph Dionisio
Senior Vice President and
Chief Information Officer

FROM: Marjorie E. McNeil MEM
Director, Facility & Physician Reimbursement

SUBJECT: Investigational Devices

Please refer to the note attached from Fred Rankin. [redacted]

For your information, the issue is as follows. We were informed by Medicare/Blue Cross that a patient's entire stay would be denied if an investigational/experimental pacer was implanted. Our contention has been that the stay should be approved and only the cost of the pacer denied since there was medical necessity for the implantation of a pacer regardless of the specific device used. [redacted]

If I can provide additional information, please let me know.

MEM/kms
M7:[illegible]

Attachments

Senate Permanent Subcommittee
on Investigations
EXHIBIT # 4

University of Washington Correspondence

INTERDEPARTMENTAL

RECEIVED
JAN 26 1990
DENNIS STILLMAN
ASSOCIATE ADMINISTRATOR

January 25, 1990

TO: Gust Bardy, MD
Peter Kudenchuk, MD
Leon Greene, MD

FROM: Lynn Poser, Director
Admitting/Financial Counseling

SUBJECT: PCD Implantable Defibrillators

As I learned last week, the PCD defibrillator, which is currently undergoing clinical trials, has now been implanted in ten patients at UWMC. Since this device is considered investigational, Medicare (and Medicaid) will not cover admissions for PCD placement. Beginning today, and based on established procedures, patients with Medicare who are scheduled for PCD implants will be asked to sign a non-covered service agreement prior to surgery and will be advised of their financial responsibillty for the admission. For scheduled admissions, the patient will be asked to pay a preadmission deposit totalling 75% of the estimated charges. The average total charges for the admissions so far has been $64,000.

Our knowledge that the PCD implants are considered a non-covered service by Medicare will prohibit the medical center and University Physicians from billing Medicare for any future admissions. In the absence of a signed noncovered services agreement we will also not be able to look to the patient for payment. I'm sure you will understand that the medical center cannot support the write-off of $50,000 to $75,000 per admission.

I am requesting that your patient care coordinator be responsible for informing the financial counselor when any patient is scheduled for a PCD implant so the necessary financial arrangements can be made prior to surgery.

LP/cr
cc: Eric Larson, MD
Dennis Stillman
Brian McKenna

Senate Permanent Subcommittee on Investigations
EXHIBIT # 5

University of Washington Correspondence

INTERDEPARTMENTAL

January 25, 1990

TO: Dennis Stillman
Associate Administrator

FROM: Lynn Poser, Director
Admitting

SUBJECT: Transvenous PCD Implantable Defibrillators

As we discovered last week, the Cardiology Service began admitting patients in November, 1989 for placement of PCD cardiac defibrillators. Since this device is still undergoing clinical trials and is considered investigational by the FDA, it would not be covered by Medicare or Medicaid.

To date, eight patients have been admitted for placement of the PCD. The total charge for the implant item is $28,000 ($17,500 is the manufacturer's charge to the medical center and the operating room attaches a 60% mark-up.)

Below is a summary of the patient accounts for the eight admissions.

Pt. #	Name	Admit/Discharge	Sponsor	Charges
6 65 80 47		11/6 - 12/12/89	Medicare	$ 69,245
1 69 58 44		11/11 - 12/3/89	Snohomish County	50,343
3 60 33 96		11/18 - 12/5/89	Group Health	57,229
4 70 39 65		11/22 - 12/20/89	King Cty Preferred	71,714
3 34 27 09		11/7 - 12/21/89	King County (Medicare secondary payor)	74,989
0 70 60 27		12/4 - 12/24/89	Veterans Admin.	58,390
0 06 48 79		12/6 - 12/20/89	Medicare	54,969
5 70 88 68		1/3/90 - inhouse	Group Health/ Medicare	64,000 (estimate)
				$ 501,758

With the exception of the last patient listed, all but one of the accounts are billed but not paid. For account number 6-65-80-47, Medicare has paid $40,416 (58%) and the contractual was $28,795 (42%).

Senate Permanent Subcommittee on Investigations
EXHIBIT # 6

Current issues related to PCD implants:

1) Due to the investigational status of this device, it is considered a non-covered service by Medicare. Therefore, we should not be billing Medicare. In order to bill the patient we would have to obtain an agreement that he/she would be responsible for the bill.

2) As of last week, Group Health informed us that they would not pay for an admission for services not covered by Medicare. Since the team went ahead with the procedure on Mr after being advised of the above, we should not expect to be reimbursed for his admission.

3) King County Medical is currently auditing the claim for Mr. Beytebiere to determine that the necessary EPS testing was done and that the results justify the PCD implant.

4) I have received a memo from Harborview requesting that UWMC pay HMC Cardiology for services ordered by Dr. Bardy and provided by their ECG lab during the patients admission to our facility. To date, these charges have not been added to the patient's UWMC accounts nor has HMC been paid.

Recommendations:

Unless we have specific, and preferably written, authorization from a third party payor, we should assume that admissions for PCD implants will not be covered at this time.

Medicare sponsored patients who are scheduled for elective admissions for electrophysiology testing and possible defibrillator implants will be asked to sign a non-covered services agreement at the time of admission stating that they understand that admissions for PCD implants will not be covered and that they will be responsible for the charges should they have the PCD implant.

If the admission request specifically indicates that the patient will receive the PCD implant, a deposit will be requested based on our existing policies.

Please let me know if you agree with the recommendations so I may orient the financial counselors.

LP/cr

March 19, 1990

TO: Eric Nickeson

FROM: Lisa Welborn

SUBJECT: TEC Protocols

This morning I spoke with Brian Teagarden in regard to the two protocols which were submitted to him. He gave me the following information for Blue Cross and Medicare reimbursement.

1. Blue Cross (Inpatient and Outpatient would be treated the same)

   - If the Blue Cross contract has an experimental clause then it will not be covered, otherwise it will.

2. Medicare

   - As an Outpatient procedure, this would be considered investigative and would not be covered. In order to bill for the procedure, a preliminary notice would have to be issued to the patient to notify them of the coverage denial.

   - Brian Teagarden suggested we get in contact with KePRO in regard to the Inpatient reimbursement issue. It is his opinion that if the patient is admitted solely for the TEC procedure, the reimbursement would be denied. If the patient is admitted for some other reason, he believed reimbursement would occur up to the point of the TEC procedure.

Please let me know if you need additional information.

Senate Permanent Subcommittee on Investigations
Exhibit # 7

University of Washington Correspondence

INTERDEPARTMENTAL

RECEIVED
APR 30 1990
MEDICAL DIRECTOR

Copies - Mary S.
- Dennis P.
- Lynn I
- Nancy I
5/1/90

Date: April 26, 1990

To: Eric B. Larson, M.D., M.P.H.
Medical Director
University of Washington Medical Center

From: Gust H. Bardy, M.D.
Associate Professor
Department of Medicine

RE: 3rd Party Authorization for Implantable Defibrillators

This is a follow-up to our telephone conversation of April 26, 1990 concerning the authorization of defibrillator systems implanted at the University Medical Center.

In order to standardize the approval process, my nurse, Charlie Troutman, will process the authorization for the implantation of the defibrillator systems with 3rd party payers (Medicare, Medicaid, Group Health and private insurers). After this authorization is received, it will be forwarded to Kim Baird or Andrea DeCano to be distributed to Financial Services (Becky Mounce and Lynn Poser) and Nancy Irvin. The intention is to decrease the redundancy of effort and to avoid conflicts about reimbursement for implantable defibrillator systems. The more people involved, the more difficult it becomes to get third party reimbursement.

One small but I believe important point is to call all these units "Implantable Defibrillator Systems." This is a more generic term than AICD or PCD and will avoid setting flags over the letters PCD.

I've also enclosed copies of a study done at the University of Pennsylvania reviewing defibrillator costs and how the hospital can make money or lose money. Of particular interest to us is how hospital costs decrease as defibrillator volume goes up because of a reduction in fixed overhead costs per patient.

Charlie is available at extension 8-4661 or through Harborview paging (BB 0250). My pager is 995-9835 and my extension is 8-4555. If I can be of further assistance in this matter, please do not hesitate to contact me.

cc J. Ward Kennedy, M.D.
Andrea DeCano
Kim Baird
Donna Nyenhuis, R.N.

Carl Bank
Dennis

Senate Permanent Subcommittee on Investigations
EXHIBIT # 8

Date: April 26, 1990

To: Eric B. Larson, M.D., M.P.H.
Medical Director
University of Washington Medical Center

From: Gust H. Bardy, M.D.
Associate Professor
Department of Medicine

RE: 3rd Party Authorization for Implantable Defibrillators

This is a follow-up to our telephone conversation of April 26, 1990 concerning the authorization of defibrillator systems implanted at the University Medical Center.

In order to standardize the approval process, my nurse, Charlie Troutman, will process the authorization for the implantation of the defibrillator systems with 3rd party payers (Medicare, Medicaid, Group Health and private insurers). After this authorization is received, it will be forwarded to Kim Baird or Andrea DeCano to be distributed to Financial Services (Becky Mounce and Lynn Poser) and Nancy Irvin. The intention is to decrease the redundancy of effort and to avoid conflicts about reimbursement for implantable defibrillator systems. The more people involved, the more difficult it becomes to get third party reimbursement.

One small but I believe important point is to call all these units "Implantable Defibrillator Systems." This is a more generic term than AICD or PCD and will avoid setting flags over the letters PCD.

I've also enclosed copies of a study done at the University of Pennsylvania reviewing defibrillator costs and how the hospital can make money or lose money. Of particular interest to us is how hospital costs decrease as defibrillator volume goes up because of a reduction in fixed overhead costs per patient. If we implanted an FDA approved device & the volume would be the same. If we implanted the PCD with informed authorization the volume & costs would be the same.

Copies is available at extension 8-4661 or through Harborview paging (BB 0250). My pager is 995-9835 and my extension is 8-4555. If I can be of further assistance in this matter, please do not hesitate to contact me.

cc J. Ward Kennedy, M.D.
Andrea DeCano
Kim Baird
Donna Nyenhuis, R.N.

Senate Permanent Subcommittee
EXHIBIT # 9

University of Washington Correspondence

INTERDEPARTMENTAL

April 30, 1990

TO: Dennis Stillman, CFO

FROM: Gust H. Bardy, M.D.

RE: Non-preauthorized PCD's

This letter is in regards to purchase orders for non-preauthorized PCD's. PCD's can only be preauthorized by Blue Cross, King County Medical and Group Health Central. Medicare, Pierce County, etc., do not preauthorize any implantable defibrillation systems, including the AICD. Payment for Implantable Defibrillator Systems with insurers that don't grant preauthorization usually follows chart review by the third party payers. We facilitate this retrospective approval process, in the case of medicare, by inserting a letter in the chart justifying defibrillator insertion. In the case of Pierce County etc., we typically fax a letter to them. This has proven satisfactory for reimbursement for nearly all of our AICD patients and should be the same for our PCD patients as long as attention isn't drawn to the investigational nature of the PCD. I understand that most payment is completed within 6 months, except in the case of Group Health Central where payment may take 6 to 18 months. If after this time period, it is clear that the hospital will not be paid, then I will request, from Medtronic, that the cost of the PCD be forgiven by Medtronic. Given this scenario then, purchase orders for PCD's should be allowed with or without preauthorization, as is done for AICD's, depending on what is appropriate for the patient, with the foreknowledge that in the case of the PCD, the University will likely not be held responsible for the payment to Medtronic of an investigational device should it ultimately not be reimbursed. This problem should ultimately disappear when the PCD is approved by the FDA in approximately 12 months.

cc: Eric Larsen, M.D.
J. Ward Kennedy, M.D.
Ann Uruburu, R.N.,

GT:ls/ltstill

Senate Permanent Subcommittee
on Investigations
EXHIBIT # 10

Blue Cross
of Washington and Alaska

PO Box 2847
Seattle, Washington 98111-2847
(206) 670-5524

W. Thompson
V. Hansmann
Medicare File: Medicine

RECEIVED
SEP 11 1990
Federal Medicare Intermediary
PFS BILLING

SEP 04 1990

Janet Pruitt
Patient Financial Services Manager
Billing Department
University of Washington Medical Center
9725 Third Avenue N.E. XD-01
Seattle, Washington 98115

Dear Janet:

I am writing in response to your August 1, letter requesting clarification of Medicare coverage for patients admitted for implantation of a Pacemaker Cardioverter Defibrillator which, as you state in your letter is still in clinical trials.

In reviewing the hospital manual I came across a reference which, I believe, addresses this question. Section 260.2 states that medical devices that have not been approved for marketing by the FDA are considered investigational and therefore are not considered reasonable and necessary for the diagnosis or treatment of illness or injury or to replace a malfunctioning body member. Program payment, therefore, may not be made for medical procedures using such devices.

The device itself appears to be the issue here. Until such time as it has, as a whole, been FDA approved, it does not appear that the program could make any payment when a PCD is implanted.

I hope this answers your question. If you need anything more, give me a call.

Sincerely,

Carol Walvatne

Carol Walvatne, Supervisor
Medicare Utilization/Medical Review

Enclosure

2441z:fh

cc: U5-70-88-68 Slusser, L
U5-71-77-16 Hoyt, P

Senate Permanent Subcommittee on Investigations
EXHIBIT # 11

CALIFORNIA MEDICAL REVIEW, INC.
CMRI 1776 WEST MARCH LANE • SUITE 210 • STOCKTON • CALIFORNIA 95207 • (209) 952-0263

JERROLD C. BOCCI, M.D., *President* JO ELLEN H. ROSS, *Chief Executive Officer*

CONFIDENTIAL
PURSUANT TO FEDERAL REGS.

November 5, 1991

COPY

Mr. Gordon Baker
7200 Sutter
Carmichael, CA 95608

Case Background:
Patient Name: BAKER, GORDON
HIC #: 429-74-2643A
Hospital: Sutter Memorial Hospital
Hospital Provider #: 05-0109
Admission Date: 07/11/91
Discharge Date: 07/29/91
Attending MD: Douglas Schuch, M.D.
MD License #: CAG 058003
Date MD Contact: 10/30/91

Dear Mr. Baker:

California Medical Review, Inc. (CMRI) is the Peer Review Organization authorized by the Medicare program to review inpatient hospital services provided to Medicare beneficiaries in the State of California.

Our physician reviewers denied Medicare payment for the procedure performed, on 7/19/91, ICD-9-CM Code 3794, procedure: Implantable Cardioverter/Pacemaker. There is a DRG change, see attached coding change letter.

We have also determined that as explained in "Your Medicare Handbook", the Medicare program does not pay for experimental procedures. You, if properly notified by the hospital, may be responsible for payment of these excluded service(s) as well as the deductible, co-insurance, and any convenience services and items normally not covered by Medicare.

Upon receipt of this notice, you will be or will continue to be responsible for payment of future hospitalization(s) if it is determined that the services involve the same or reasonable comparable conditions discussed below.

Our determination is based on a review of your medical records and a discussion with your attending physician which indicates that:

Services are normally excluded from coverage under Medicare coverage policies.

SMH-W709
In Response to OIG Subpoena dated 05/26/94 and Revised 7/1/94

Senate Permanent Subcommittee on Investigations

EXHIBIT # 12

If you or the attending physician disagree with our determination you may request a reconsideration. If representatives of the hospital do not agree with our determination, a reconsideration of the initial denial, or of the waiver status may be requested. Requests must be submitted in writing within 60 days from the receipt of this notice to the following address:

California Medical Review, Inc.
Northern Region
1737 North First Street, Suite 600
San Jose, CA 95112

If a review reconsideration is requested, you have an opportunity to examine and obtain a copy of all material upon which the initial determination was based. You may have to pay a reasonable fee for the reproduction of the material.

You, the patient, have the right to submit your request to the address above or you may make your request to:

1. any Social Security Office
2. any Railroad Retirement Office, if you are eligible.

Your request will be forwarded to us.

You also can have a friend, lawyer, or someone else help you. There are groups that can help you find a lawyer or give you free legal services if you qualify. There are also lawyers who do not charge unless you win your appeal. Your local Social Security Office has a list of groups that can help you with your appeal.

You have the right to request and examine your complete medical record which we relied upon in making this denial determination. Although the hospital is the official repository of the medical records relevant to stays in the facility, should you wish to examine or receive a copy of your medical record for this stay, we can provide it to you at a reasonable cost.

Sincerely,

M. Parker / (illegible)

Malcolm R. Parker, M.D.
Regional Medical Director
Northern Region

MRP/lr

cc: Ms. Dolly McDonald, Administrative Liaison, Sutter Memorial Hospital
Douglas Schuch, M.D., Attending Physician

SMH-W710
In Response to OIG Subpoena dated 05/28/94 and Revised 7/1/94

Patient Name: BAKER, GORDON
Page 3

ADDENDUM LETTER - BENEFICIARY

Date of the Letter: November 5, 1991

The regulatory basis for CMRI's initial denial determination was 42 CFR 466.71 (a) (1): Determine whether services are reasonable or medically necessary.[1]

After review of the hospital record, it has been determined that payment for the procedure of Implantable Cardioverter/Pacemaker performed on 7/19/91 during the admission of 7/11/91 to 7/29/91 at Sutter Memorial Hospital is denied by medicare. This is an experimental procedure and not covered by the Medicare program.

[1]42 CFR 466.71 (a) (1): "Whether the services are or were reasonable and medically necessary for the diagnosis and treatment of illness or injury or to improve functioning of a malformed body member, or (with respect to pneumococcal vaccine) for prevention of illness or (in the case of hospice care) for the palliation and management of terminal illness."

SMH-W711
In Response to OIG Subpoena dated 09/29/94 and Revised 7/11/95

BAPTIST MEDICAL CENTER OF OKLAHOMA

December 12, 1991

R.C. Brown, MD
3433 N.W. 56th # 800
Oklahoma City, OK 73112

Dear Dr. Brown:

Recently many questions have arose concerning the filing of hospital bills when non FDA approved procedures or devices are used.

This should be of great concern to all hospitals since the improper handling of such patient bills can lead to severe consequences.

I will discuss the billing of non approved procedures and devices from the standpoint of Medicare and commercial insurance patients.

Medicare Patients

All Medicare patients who undergo a non FDA approved procedure or device must have a " no pay claim " filed by the hospital. This results in no reimbursement to the hospital, but updates Medicare as to the hospitalization and procedure of the Medicare recipient.

The filing of non FDA approved procedures or devices as " for pay claims " is considered as follows:

1. Fraud - If the hospital knowingly files a claim as a " for pay claim " when a non FDA approved procedure or device is present.

2. Error - If the hospital unknowingly files a claim as a " for pay claim " when a non FDA approved procedure or device is present.

Senate Permanent Subcommittee on Investigations
EXHIBIT # 13

Note: Under both 1 and 2 above the hospital will be required to refund back all reimbursement to the Federal Government when the inappropriate filing is detected. It is common to have to refund reimbursements even on claims as old as three or four years.

Commercial Insurance Patients

All commercial insurance patients who receive non FDA approved procedures and devices are billed to the respective insurance company in the exact same fashion as approved procedures and devices.

It is the burden of the insurance company to detect the non FDA approved procedure or device and handle the claim with the benefits of the insurance policy at hand.

However most insurance companies can detect non approved procedures and devices and reject the claim based on such non coverage in the insurance policy. This puts the entire financial burden upon the patient which generally leads to bad debt write offs.

I am aware that many hospitals are presently filing such claims as " for pay claims " due to the following circumstances:

1. Salesman convince physicians and hospitals to use non FDA approved devices and bill as " for pay claims" because other hospitals are doing so. (This is gross misrepresentation on the part of the salesman).

2. Many business office billers do not readily recognize the procedure or device as non FDA approved and in error bill as a " for pay claim ."

3. Many Business Office Managers/Directors do not recognize the seriousness of billing these items as " for pay claims."

Policy Of Baptist Medical Center On Billing Non FDA Approved Procedures And Devices

The business office will bill all non FDA approved procedures and devices on Medicare patients as " non pay claims " which results in no reimbursement to the hospital.

The business office will bill all non FDA approval procedures and devices on commercial insurance patients in the normal fashion and let the individual insurance company determine if it is a payable claim under its specific coverage.

In summary it is illegal to bill Medicare for non FDA approved procedures and devices as a " for pay claim." It is in our best interest to collect appropriate deposits for all patients deciding to receive non FDA approved procedures and devices.

In my opinion many hospitals will be faced with large dollar refunding to Medicare in the next two to four years when such misfiled claims are detected.

I hope the above information has helped to understand Baptist Medical Center's billing policy on non FDA approved procedures and devices.

Sincerely,

Darrell Maier, CMPA
Director Business Office

MEDICARE FRAUD ALERT

RESTRICTED MEDICARE FRAUD ALERT

RMFA:94-1 DATE: March, 1994

THIS ALERT IS CONFIDENTIAL. ITS DISTRIBUTION IS LIMITED TO HCFA REGIONAL OFFICES, MEDICARE CARRIERS AND INTERMEDIARY FRAUD UNITS, PEER REVIEW ORGANIZATIONS AND THE OFFICE OF INSPECTOR GENERAL. THIS ALERT IS TO GO TO ALL FRAUD UNIT MANAGERS IMMEDIATELY. THIS ALERT IS NOT INTENDED TO BE USED AS A BASIS FOR THE DENIAL OF ANY CLAIM OR ANY ADVERSE ACTION AGAINST ANY PROVIDER. SUCH DECISIONS MUST BE BASED ON FACTS INDEPENDENT OF THIS ALERT.

SUBJECT: Implantable Cardioveter Defibrillator (ICD) Systems

ACTIVITY: The Medicare program has been billed by some providers for ICD systems that had not been approved, at the time of implantation, by the Food and Drug Administration (FDA).

Initial implantation of these devices usually requires an inpatient hospital stay. Outpatient stays to adjust device and leads have also been identified. ICD-9-CM Code 37.94 identifies the procedure; however, it is necessary to review the medical documentation (progress notes, operative reports, discharge summaries, and patient consent forms) to identify the manufacturer, make and model number of the generator and lead system.

These unapproved devices may have been implanted in beneficiaries across the nation.

The intermediary estimates an overpayment $4.7 million in its jurisdiction.

EQUIPMENT PARAMETERS

A list of commercially available ICD Systems approved by the FDA and the date of approval follows. Updates to this list will be provided by the Benefit Integrity Staff.

Manufacturer	Model Name & Number	Lead System	FDA Approval Date
Cardiac Pacemakers Inc. (CPI)	AID-B, AID-BR	Epicardial	10/04/85
CPI	Ventak AICD Models 1500, 1510 & 1520 (versions of AID-B & AID-BR)	Epicardial	3/27/86
CPI	Ventak AICD Model 1550	Epicardial	11/08/88
CPI	Ventak AICD Model 1555	Epicardial	9/13/90
CPI	Ventak P AICD Model 1600	Epicardial	5/02/91
CPI	0060 ENDOTAK Lead System (Ventak AICD Models 1550, 1555 & 1600)	Non-thoracotomy	8/23/93

Senate Permanent Subcommittee on Investigations
EXHIBIT # 14

MEDICARE FRAUD ALERT

Medtronic, Inc.	PCD Models 7216 A & 7217 B	Epicardial	2/11/93
Medtronic, Inc.	Medtronic Transvene System (PCD Model 7217 B)	Non-thoracotomy	12/09/93
Ventritex, Inc.	Cadence Tiered Therapy Defibrillator System	Epicardial	5/30/93

This list is complete as of February 17, 1994. ICDs not on this list have not been approved by the FDA.

APPLICABLE REQUIREMENTS

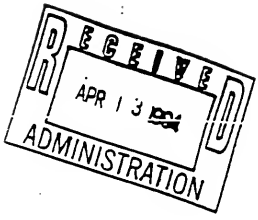
Section 3152.1 of the MIM, Section 2303.1 of the MCM, and Section 260.1B Medicare Hospital Manual state:

> "...devices which have not been approved for marketing by the Food and Drug Administration are considered investigational by Medicare and are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures or services performed using devices which have not been approved by the FDA."

CONTACTS: Gerry Gibson, OIG, (206) 615-2259

NOTICE: THIS FRAUD ALERT CONTAINS CONFIDENTIAL INFORMATION EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT. ITS CONTENTS SHOULD NOT BE REPRODUCED OR RELEASED TO ANY OTHER PARTY WITHOUT WRITTEN APPROVAL OF THE BENEFIT INTEGRITY STAFF. DISCLOSURE TO UNAUTHORIZED PERSONS IS PROHIBITED AND MAY BE IN VIOLATION OF THE CRIMINAL PROVISIONS OF THE PRIVACY ACT.

Sutter Memorial Hospital
MEMORANDUM



DATE: April 13, 1994

TO: Pat Fry

FROM: Mark W. Riege MR

SUBJECT: Investigational electrophysiology devices

As the attached documents support and my recent dialogue with Pat Maydahl and Arjun Sharma,MD have confirmed, there is a conundrum that we are operating under. Medicare clearly does not reimburse for non FDA approved and/or investigational devices. We are however, placing these devices and billing medicare for them. To avoid a denial by Medicare we do not keep the patient consent that identifies the device as investigational in the chart. The consents are kept with SIMR. CMRI therefore, would not have ready access to information that identifies the devices as investigational.

There is a double standard in the medical community. Evidently, University hospitals enjoy an unwritten exemption and Sequoia Hospital in the South Bay has an "understanding" with CMRI to overlook this policy.

We have installed approximately 25 - 30 such devices in the past year and one half. Some of these devices will become FDA approved by the time we could potentially be audited. Clearly, by the letter of the law we are at risk. However, there is obviously no communication between the FDA and HCFA which would easily allow HCFA to identify the devices and given the large number of exemptions currently occurring, I would think our overall risks are small.

Dr.'s Sharma and O'Neil are very active in using investigational devices and have a good relationship with SIMR. Their business is important to the lab here and to halt this activity would clearly drive their business elsewhere.

I will prepare a more detailed list of patients, payors and devices for our joint review.

Let me know if you have any additional questions.

Senate Permanent Subcommittee
on Investigations
EXHIBIT # 15

Date of Service	Patient Name	Date of Birth	Social Security #	Device Name	Manufacturer Name / Address	Responsible Physician	Clinical Investigator	DRG	Total Charges
72482				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Farah Tony MD	Rodney H. Randall, MD	112	$10,791.00
111193				Cardiac Pacemakers Inc #1825	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		112	$33,837.00
12991				TEC	International Technologies / 3574 Ruffin Road San Diego, CA 92123	Gay Thomas C	Gay	104	10.00
22093				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Salvoza Manuel		112	$33,837.00
120293				Cardiac Pacemakers Inc #1825	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		112	$9,334.00
80592				RES PTCA Balloon	Cordis / P.O. Box 527048 Miami, FL 33152	Beegy Richard J MD		104	10.00
80792				REX PTCA Balloon	Cordis / P.O. Box 527048 Miami, FL 33152	Iacorvati Robert DO		112	$25,381.00
81192				Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Maher Thomas O		112	$25,381.00
71089				Medtronic sp 105 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Magovern George Sr MD		104	$44,782.00
71893				CPI #0043 and #0063	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		109	$38,580.10
91492				Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Burkholder John A		104	$116,354.00
31591				Cardiac Pacemakers Inc. #1400	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		104	$44,335.00
11191				Cardiac Pacemaker Inc #1700	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		104	$148,254.00
61192				Cardiac Pacemaker Inc #1705	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		104	$67,735.00
120193				World Pass PTCA	Cordis / P.O. Box 527048 Miami, FL 33152	Lasorda David DO	Lasorda	126	$36,447.00
90892				Medtronic sp 105 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Magovern James MD		112	10.00
40792				Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Maher Thomas O		104	$70,735.00
120888				Cardiac Pacemakers Inc. #1400	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$44,342.00
61493				Cardiac Pacemakers Inc #1825	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$39,181.88
71190				Medtronic sp 105 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Magovern James MD		104	$79,451.00
31292				Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Burkholder John A		104	$114,785.30
61992				REX PTCA Balloon	Cordis / P.O. Box 527048 Miami, FL 33152	Pecora Michael MD		104	$44,131.00
42789				Cardiac Pacemakers Inc. #1600	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		112	$11,205.00
111892				Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Burkholder John A		105	$178,841.53
82091				Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Burkholder John A/ Chanerdas John MD		104	$67,354.00
110791				Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Hart Wall J	Hart	112	$38,305.00
92992				Ventritex V-100	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Burkholder John A		104	$75,849.00
92492				CPI #0042 and #0043 (New Implant)	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		104	$80,340.00
71393				Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Maher Thomas O		104	$98,340.00
82090				TEC	International Technologies / 3574 Ruffin Road San Diego, CA 92123	Maher Thomas O		104	$40,198.00
111991				Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Pecora Michael MD	Pecora	112	$4,042.80
71993				Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Burkholder John A		104	$72,244.00
113093				World Pass PTCA	Cordis / P.O. Box 527048 Miami, FL 33152	Burkholder John A		104	$74,074.00
20493				Ventritex V-100C	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Paulowski John MD	Paulowski	112	10.00
32191				Cardiac Pacemaker Inc #1300	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		104	$110,044.00
120793				Cardiac Pacemaker Inc #1705	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$107,874.00
92491				Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Pecora Michael MD	Donohue	112	$16,824.00
81991				Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Salvoza Manuel	Salvoza	112	$33,837.00
32592				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Gay Thomas C		112	$33,349.00
22692				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Gay Thomas C		112	$37,349.00
91393				Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Byrne C. Donohue, MD	Donohue	112	$21,932.00
90188				Cordis/ Telectronics 5450A	Tel Lectronics Pacing Systems Cordis / 7400 S. Tucson Way Englewood CO 80112	Burkholder John A		104	$24,548.01
22092				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Rodney H. Randall, MD		112	$11,958.00
22492				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Farah Tony MD		112	$14,833.00
82191				Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Farah Tony MD	Farah	112	$13,802.00
111191				Ventritex V-100	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Magovern James MD		104	$108,572.00
91791				Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Hart Wall J	Hart	112	$27,293.49
113093				World Pass PTCA	Cordis / P.O. Box 527048 Miami, FL 33152	Pecora Michael MD	Pecora	112	10.00
72789				Cardiac Pacemakers Inc. #1400	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		105	$81,441.80
90991				Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Pecora Michael MD	Pecora	112	$27,049.00
22092				Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Burkholder John A		104	$44,439.00
120892				CPI #0042 and #0043	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$73,837.00
72693				Cardiac Pacemakers Inc #1825	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$48,032.00
12092				Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Maher Thomas O		104	$67,132.00
72092				Cardiac Pacemaker Inc #1705	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$67,214.00
82492				Ventritex V-100	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Burkholder John A		104	$99,854.00
102490				TEC	International Technologies / 3574 Ruffin Road San Diego, CA 92123	Salvoza Manuel	Rodney H. Randall, MD	112	$12,742.00
21792				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Iacorvati Robert DO		112	$13,284.00
120691				Cardiac Pacemaker Inc #1705	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		468	$89,549.00
111792				Ventritex V-1000	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Burkholder John A		104	$79,843.98
21192				Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Burkholder John A		104	$82,142.00
22492				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Iacorvati Robert DO		112	$17,395.00
92391				Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Farah Tony MD	Farah	112	$23,596.00
22193				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Lasorda David DO		112	$11,295.43

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Senate Permanent Subcommittee on Investigations
EXHIBIT # 18

	Patient Name	Date of Birth	Social Security #	Device Name	Manufacturer Name / Address	Responsible Physician	Clinical Investigator	DRG#	Total Charges
92				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Incorvati Robert DO		112	$32,292.00
89				Telectronics - 4202	Tel Lectronics Pacing Systems / 7400 S. Tucson Way Englewood CO 80112	Burkholder John A		112	$63,214.03
90				TEC	International Technologies / 3574 Raffin Road San Diego, CA 92123	Lasorda David DO	Lasorda	105	$63,214.03
88				Telectronics - 4282	Tel Lectronics Pacing Systems / 7400 S. Tucson Way Englewood CO 80112	Burkholder John A		112	$31,658.00
88				Medtronic sp 103 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Magovern James MD		104	$57,477.01
88				Telectronics - 4202	Tel Lectronics Pacing Systems / 7400 S. Tucson Way Englewood CO 80112	Maher Thomas D		108	$90,737.49
94				Cardiac Pacemakers Inc #1625	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas D		104	$53,242.30
93				Ventritex V-100C	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Burkholder John A		104	$0.00
91				Cardiac Pacemakers Inc. #1600	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Gay Thomas C	Farah	112	$44,933.00
92				Medtronic #7217B	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Burkholder John A		105	$29,488.00
93				Cardiac Pacemakers Inc #1625	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas D		104	$120,114.00
192				TEC	International Technologies / 3574 Raffin Road San Diego, CA 92123	Lasorda David DO	Lasorda	104	$32,937.00
192				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Salvoza Manuel		112	$23,113.00
192				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Lasorda David DO/ Farah Tony MD		112	$13,254.00
192				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Incorvati Robert DO		112	$29,376.00
192				BIX PTCA Balloon	Cordis / P.O. Box 527048 Miami, FL 33152	Farah Tony MD	Lasorda	107	$49,736.00
192				Ventritex V-100	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Burkholder John A		112	$12,958.00
191				Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Gay Thomas C	Farah	104	$31,559.00
192				Ventritex V-100	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Maher Thomas D		112	$33,163.00
188				Cordis/ Telectronics 1430A	Tel Lectronics Pacing Systems Cordis / 7400 S. Tucson Way Englewood CO 80112	Maher Thomas D		104	$103,819.00
192				Ventritex V-100	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Maher Thomas D		104	$42,105.30
192				Ventritex V-100C	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Maher Thomas D		104	$93,017.00
193				Cardiac Pacemakers Inc #1625	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$84,696.00
189				Cardiac Pacemakers Inc #1625	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Gay Thomas C		105	$34,801.00
895				Cardiac Pacemakers Inc. #1600	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$83,516.00
790				Ventritex V-100C	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Maher Thomas D		104	$93,314.18
888				TEC	International Technologies / 3574 Raffin Road San Diego, CA 92123	Randall Rodney R	Randall	112	$36,336.00
693				Telectronics - 4202	Tel Lectronics Pacing Systems / 7400 S. Tucson Way Englewood CO 80112	Burkholder John A		112	$10,319.30
393				Medtronic #7217B	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Maher Thomas D		104	$305,597.48
391				Medtronic #7217B	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Maher Thomas D		104	$81,226.00
492				Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Incorvati Robert DO		104	$109,239.00
892				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Smith Gregory MD	Incorvati	112	$19,588.00
890				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Magovern Jr. George J./ Gay Thomas C		112	$13,064.00
891				TEC	International Technologies / 3574 Raffin Road San Diego, CA 92123	Farah Tony MD		104	$33,316.00
889				Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Byron C. Donohue, MD	Farah	112	$18,730.00
395				Cardiac Pacemakers Inc. #1600	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A	Lasorda	112	$32,640.00
395				Cardiac Pacemakers Inc #1625	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$106,658.07
869				Cardiac Pacemakers Inc. #1600	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$0.00
093				World Pass PTCA	Cordis / P.O. Box 527048 Miami, FL 33152	Pecora Michael MD		105	$62,315.78
792				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Salvoza Manuel	Pecora	479	$0.00
1791				Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Salvoza Manuel	Rodney R. Randall, MD	112	$13,270.00
1192				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Lasorda David DO	Salvoza	112	$49,278.00
1792				Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Lasorda David DO		112	$34,697.00
1992				Cardiac Pacemaker Inc #1700	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486			112	$34,697.00
1891				Cardiac Pacemaker Inc #1700	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas D		104	$83,800.00
1291				Medtronic #7217B	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Burkholder John A		104	$94,547.00
1193				PI #8082 and #8083	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$122,781.00
2390				TEC	International Technologies / 3574 Raffin Road San Diego, CA 92123	Randall Rodney R	Randall	112	$14,873.10
1090				Cardiac Pacemakers Inc. #1600	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Pecora Michael MD	Rodney R. Randall, MD	112	$22,299.00
2892				Ventritex V-100	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Burkholder John A		104	$125,993.90
1792				Medtronic sp 103 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Maher Thomas D		104	$130,143.88
2191				PI #8082 and #8083	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Magovern James MD		104	$96,386.09
0588				Telectronics/Cordis #284A	Tel Lectronics Pacing Systems / 7400 S. Tucson Way Englewood CO 80112	Burkholder John A		104	$238,893.00
0793				Medtronic #7217B	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Burkholder John A		104	$95,298.97
0291				Medtronic #7217B	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Maher Thomas D		104	$0.00
2292				Cardiac Pacemaker Inc #1705	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas D		104	$66,545.00
1091				Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Burkholder John A		104	$117,501.00
0689				Telectronics - 4202	Tel Lectronics Pacing Systems / 7400 S. Tucson Way Englewood CO 80112	Donohue Bryan MD	Donohue	112	$10,533.00
0591				Medtronic #7217B	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Burkholder John A		104	$61,570.34
0992				TEC	International Technologies / 3574 Raffin Road San Diego, CA 92123	Burkholder John A		104	$54,711.00
1088				electronics/Cordis #284A	Tel Lectronics Pacing Systems / 7400 S. Tucson Way Englewood CO 80112	Lasorda David DO	Rodney R. Randall, MD	112	$26,131.00
1091				Ventritex V-100	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Burkholder John A		108	$84,007.42
1193				World Pass PTCA	Cordis / P.O. Box 527048 Miami, FL 33152	Maher Thomas D		104	$75,479.00
						Incorvati Robert DO	Incorvati	113	$0.00

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Patient Name	Date of Birth	Social Security	Device Name	Manufacturer Name / Address	Responsible Physician	Clinical Investigator	DRG	Total Charges
			Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Pecora Michael MD	Donohoe	112	$9,391.00
			Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Hart Neil J	Donohoe	112	$22,613.00
			TEC	Interventional Technologies / 3574 Ruffin Road San Diego, CA 92123	Lasorda David DO	Lasorda	112	$30,926.00
			Cardiac Pacemakers Inc. #1400	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55408	Burkholder John A		104	$72,232.80
			Medtronic sp 105 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Nagovern James MD		109	$48,752.90
			Medtronic sp 105 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Nagovern James MD		104	$131,304.75
			Medtronic sp 105 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Nagovern James MD		104	$37,878.00
			CPI #0043 (Scm Implant)	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		104	$84,543.00
			Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Maher Thomas O		104	$81,258.00
			Medtronic sp 105 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Nagovern James MD		108	$77,346.00
			Medtronic sp 105 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Nagovern James MD		108	$97,558.00
			World Pass PTCA	Cordis / P.O. Box 527048 Maimi, FL 33152	Salvora Manuel	Saldora	112	$0.00
			Cardiac Pacemakers Inc #1425	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		110	$118,471.00
			Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Maher Thomas O		104	$73,874.00
			Cardiac Pacemakers Inc #1425	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		103	$47,436.00
			CPI #0042 and #0043	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$88,781.00
			CPI #0042 and #0043	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		110	$75,199.00
			Cardiac Pacemaker Inc #1705	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		104	$110,711.00
			CPI #0042 and #0043 (Scm Implant)	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		104	$110,711.00
			Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Burkholder John A		104	$65,109.00
			Cardiac Pacemakers Inc #1625	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$0.00
			World Pass PTCA	Cordis / P.O. Box 527048 Maimi, FL 33152	Salvora Manuel	Saldora	112	$0.00
			Cardiac Pacemakers Inc. #1400	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		483	$407,575.00
			Cordis/ Telectronics #430A	Tel Lectronics Pacing Systems Cordis / 7400 S. Tucson Way Englewood CO 80112	Burkholder John A		109	$38,942.40
			Cardiac Pacemakers Inc #1625	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$0.00
			TEC	Interventional Technologies / 3574 Ruffin Road San Diego, CA 92123	Silvora Manuel	Randall	104	$49,348.00
			Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Donohoe Bryan MD	Donohoe	112	$13,644.00
			Cardiac Pacemakers Inc. #1400	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$77,137.50
			Ventritex V-100	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Bonnet Christopher MD		120	$75,855.00
			Cardiac Pacemakers Inn #1625	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		110	$46,782.00
			Rally PTCA Balloon	Scimed Life Systems, Inc. / 13000 County Rd. 6 Minneapolis, MN 55441	Hart Neil J		112	$12,766.00
			REX PTCA Balloon	Cordis / P.O. Box 527048 Miami, FL 33152	Hart Neil J	Hart	112	$11,148.00
			Cordis/ Telectronics #430A	Tel Lectronics Pacing Systems Cordis / 7400 S. Tucson Way Englewood CO 80112	Burkholder John A		114	$32,233.30
			Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Pecora Michael MD	Pecora	112	$3,274.00
			REX PTCA Balloon	Cordis / P.O. Box 527048 Miami, FL 33152	Farah Tony MD	Farah	112	$11,044.00
			Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Bonnet Christopher MD/ Burkholder John A		110	$75,917.00
			Cardiac Pacemakers Inc #1425	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		110	$70,241.00
			TEC	Interventional Technologies / 3574 Ruffin Road San Diego, CA 92123	Maher Thomas O	Salvora	110	$34,293.00
			World Pass PTCA	Cordis / P.O. Box 527048 Miami, FL 33152	Salvora Manuel	Saldora	112	$0.00
			TEC	Interventional Technologies / 3574 Ruffin Road San Diego, CA 92123	Randall Rodney M	Randall	112	$22,467.00
			Medtronic sp 105 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Nagovern James MD		483	$309,104.08
			TEC	Interventional Technologies / 3574 Ruffin Road San Diego, CA 92123	Hagerty Michael MD	Randall	112	$5,465.00
			Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Incorvati Robert DO	Incorvati	112	$14,729.50
			TEC	Interventional Technologies / 3574 Ruffin Road San Diego, CA 92123	Gay Thomas C	Gay	112	$24,019.00
			World Pass PTCA	Cordis / P.O. Box 527048 Maimi, FL 33152	Begg Richard J MD	Begg	112	$0.00
			Medtronic sp 105 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Nagovern James MD		104	$127,359.00
			Cardiac Pacemaker Inc #1700	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		105	$31,148.00
			Telectronics/Cordis #284A	Tel Lectronics Pacing Systems / 7400 S. Tucson Way Englewood CO 80112	Burkholder John A		105	$43,346.83
			Medtronic sp 105 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Nagovern James MD		108	$75,802.00
			Solo Balloon catheter	U.S. Catheter Instruments CR Bard, Inc. / P.O. Box 92146 Chicago, IL 60675	Pecora Michael MD	Pecora	112	$10,985.00
			TEC	Interventional Technologies / 3574 Ruffin Road San Diego, CA 92123	Donohoe Bryan MD/ Randall Rodney M		109	$13,133.01
			Cardiac Pacemakers Inc #1425	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		104	$0.00
			Cardiac Pacemaker Inc #1705	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Burkholder John A		104	$108,563.00
			CPI #0042 and #0043	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas		104	$70,171.00
			World Pass PTCA	Cordis / P.O. Box 527048 Maimi, FL 33152	Salvora Manuel	Saldora	112	$0.00
			World Pass PTCA	Cordis / P.O. Box 527048 Maimi, FL 33152	Begg Richard J MD	Begg	112	$0.00
			World Pass PTCA	Cordis / P.O. Box 527048 Maimi, FL 33152	Pasiowski John MD	Pasiowski	112	$0.00
			TEC	Interventional Technologies / 3574 Ruffin Road San Diego, CA 92123	Donohoe Bryan MD	Donohoe	112	$8,308.00
			Cordis/ Telectronics #430A	Tel Lectronics Pacing Systems Cordis / 7400 S. Tucson Way Englewood CO 80112	Maher Thomas O		109	$36,804.30
			Ventritex V-100	Ventritex / 709 E. Evelyn Ave. Sunnyvale, CA 94086	Maher Thomas O		104	$49,251.00
			Cardiac Pacemakers Inc #1425	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		104	$70,119.00
			Medtronic #72178	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Maher Thomas O		104	$80,938.00
			Cardiac Pacemakers Inc. #1400	Cardiac Pacemakers, Inc. / P.O. Box A-9228 Minneapolis, MN 55486	Maher Thomas O		104	$143,499.00
			Medtronic sp 105 pacemakers	Medtronic / P.O. Box 7777-W4110 Philadelphia, PA 19175	Nagovern James MD		108	$74,472.00

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March 13, 1996

Harold Damelin
Chief Counsel and Staff Director
Permanent Subcommittee on Investigations
United States Senate
Committee On Governmental Affairs
Washington, D.C. 20510-6250

Re: Correction To Mr. Rieger's February 14, 1996 Testimony

Dear Harry:

Thank you for sending me a copy of Mr. Rieger's February 14, 1996 testimony before the Senate's Permanent Subcommittee on Investigations. As I mentioned in our telephone conversation last week, Mr. Rieger made an inadvertent error in his testimony concerning the number of documents he reviewed prior to writing his April 13, 1994 memorandum to Patrick Fry. Mr. Rieger testified that he had attached one document to his memorandum to Mr. Fry. (Transcript at p. 128.) Mr. Rieger described that document as a legal opinion. (Transcript at p. 128.)

Mr. Rieger forgot that there were actually two documents attached to his April 13th memorandum to Patrick Fry. The second document concerned a request for a legal opinion. As you are aware, the existence of these two documents had been disclosed to the Permanent Subcommittee in Sutter Memorial Hospital's privilege log, tendered prior to Mr. Rieger's testimony.

Please let me know if the Subcommittee would like Mr. Rieger to make the correction to his testimony at page 128 of the transcript or whether this letter is sufficient to establish a correction for the record. I look forward to your reply.

Very truly yours,

Gordon A. Greenberg

for SHEPPARD, MULLIN, RICHTER & HAMPTON LLP

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Senate Permanent Subcommittee
on Investigations
EXHIBIT # 25

Statement of
Senator Orrin Hatch
Permanent Subcommittee on Investigations
Senate Committee on Governmental Affairs
Hearings on Improper Medicare Billings by Hospitals Nationwide
for Investigational Devices and Procedures
February 14, 1996

Mr. Chairman and Members of the Committee:

Today we will hear about improper Medicare billings by hospitals for investigational devices and procedures. Some of the information will be disturbing, and lead to cries that many research hospitals and the physicians who work in them are actively participating in wholesale fraud against the government. I urge the Committee to bear in mind that these activities, while utterly reprehensible, represent a minority of cases when compared to the literally thousands of procedures for which Medicare reimburses each day.

Let me make clear, I recognize that, In some cases, it is sadly true that greed has led people and institutions to knowingly defraud the government and those cases should be punished under the law. However, I fear that all research institutions and all the people within them will be painted today with too wide a brush and that is why I want to make this statement today.

I think it is necessary to separate those who may be engaging in wholesale fraud from those who either did not understand the rules or who disagreed with the interpretation of the rules that will be presented today.

The hearing today will focus on whether hospitals billed Medicare for investigational devices which HCFA believe had clearly been stated as not eligible for payment. In fact, the Health Care Financing Administration (HCFA) published a paragraph in the Hospital Reimbursement Manual in 1986 that said the Medicare program would not pay for "medical devices which have not been approved for marketing by the FDA." That statement may not be as clear as it sounds. Let me examine this issue further.

By statute and regulation, Medicare covers all services which are considered "reasonable and necessary." The compendium of Medicare's specific coverage policies, the *Coverage Issues Manual*, is silent on the reimbursement for investigational devices. The only reference to reimbursement for investigational devices was the above mentioned revision to the Hospital manual (§260.1B), which stated:

"Medical devices which have not been

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> approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary...Program (Medicare) payment, therefore, may not be made..."

This two - sentence statement was a revision to a three - inch thick manual which has been revised several hundred times since its initial creation. It is not a regulation, and does not have the force of law.

In fact, even hospitals attempting to comply with the 1986 policy statement may have had difficulty understanding HCFA's intentions. HCFA states that investigational devices will not be paid for until approved for marketing by the FDA. Since FDA regulations expressly permit manufacturers to charge for investigational devices, hospitals could reasonably have concluded that there was "marketing approval" from the FDA. A hospital accountant may have made a reasonable effort to comply with HCFA policy and think the FDA rule that permits the sale of devices in clinical trials constitutes "marketing approval."

It was not until 1989 that HCFA published a proposed regulation which would have denied coverage for most investigational devices. However, this proposed regulation was not finalized.

In June 1994 the Office of the Inspector General of the Department of Health and Human Services announced a nationwide investigation into the billing practices of hospitals and physicians for non-FDA approved devices. We are here today to see the results of an almost two-year-old investigation, which is still ongoing.

In December of 1994, after the investigation was begun, HCFA issued an 11 page "compilation and explanation of existing policies.." which stated, among other things, they would not pay for investigational devices.

However, I want to give you an example of the ongoing confusion on this issue.

During the late 1980's and early 1990's, HCFA required special Peer Review Organization (PRO) review of pacemaker implants, including 100 percent pre-admission review. This means that hospitals could not be paid for pacemakers without submitting a form specifying the manufacturer and model of a pacemaker along with the claim form. In spite of the fact that many of these forms included documentation that the pacemaker was investigational, a vast majority of these claims were paid, including claims for investigational devices.

If Medicare intermediaries, the arbitrators of the billing rules for the system, do not understand HCFA's "clear" policy, how are the hospitals supposed to?

Some hospitals felt they had nowhere else to turn to and 25 hospitals filed a lawsuit arguing that the old policy barring payment for investigational devices was illegal. They based this claim on the assertion that HCFA's decision not to pay for these devices never went through government rulemaking procedures. This lawsuit is still pending.

As concerns over this issue continued to grow, the Physician Payment Review Commission (PPRC) recommended to Congress that we provide Medicare coverage for experimental devices under some circumstances (PPRC *Annual Report to Congress*, 1995). PPRC recognized that there was a valid justification for the use of some investigational devices in Medicare beneficiaries and therefore, payment was justified in these instances.

PPRC stated:

> "devices differ from drugs in that they are typically improved incrementally and often. Each new generation of a device must have its safety and efficacy confirmed in formal studies. The difference from the previous generations device is often small, however, so that the safety and efficacy of the new one are often expected to be similar if not better. In addition, devices are typically produced by small companies that lack the resources to fund all the costs associated with a continuing cycle of improvements and testing."

PPRC recommended:

> "For selected medical devices and procedures of unproven efficacy, partial coverage in the context of approved research trials would benefit patients and medical innovators by supporting faster evaluation of new technologies. this would provide earlier access for all patients to services proven beneficial, and would

> help identify nonbeneficial services before their use becomes widespread....The commission recommends that Medicare pay the lesser of the cost of standard care or the experimental service in approved studies testing investigational devices as well as other services not yet covered by HCFA."

Later that year, I introduced S. 955, which would provide payment for investigational devices that were used instead of a covered device or procedure. Likewise, Rep. William M. Thomas introduced H.R. 1744, a slightly different proposal which would require that Medicare pay for the use of any IDE device used in place of an FDA-approved device. In Rep. Thomas' bill, payment would not be permitted above the cost of the approved device.

In response, HCFA published regulations September 19, 1995 extending payment for about 95 percent of all investigational devices for Medicare beneficiaries (60 *Federal Register* 48417). This rule became effective November 1, 1995.

Under the regulation, the FDA assigns all devices granted an investigational device exemption (IDE) into either Category A (experimental/investigational devices) or Category B (non-experimental/investigational).

Devices in Category A are considered "an innovative device...for which 'absolute risk' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective.)"

Category A devices, as well as all services related to those devices, are not paid for by Medicare. In addition, carriers and intermediaries do not have any discretion regarding payment for these devices.

Devices in Category B, on the other hand, are paid for by Medicare. These devices are those "for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type." (60 *Federal Register* 48417).

To date, about 95 percent of investigational devices are categorized as Category B devices, and are paid for by Medicare.

Why did HCFA change its policy regarding reimbursement for investigational devices? We can get a better picture of that by looking at an example of the investigational devices included in this issue.

One of the devices that sparked this debate is the implanted cardiac defibrillator. This device is implanted in people who suffer a life-threatening condition known as ventricular tachycardia, a dangerous abnormal heart beat. The device is intended to detect when the person's heart beat goes into this abnormal rhythm, then deliver an electrical shock directly to the heart to change the heart beat back into a normal rhythm. Without the device, or if the device fails to work, the person can experience sudden death.

The investigational device was, in fact, a newer version of an earlier approved model. Due to FDA regulations, the newer model must undergo testing before it becomes fully approved.

Many research hospitals participated in trials using the improved models - they would pay for the newer device (as allowed by FDA regulation), then implant the newer device under a study protocol. Medicare paid the hospital the same, regardless of which device was used, even if the new device cost more than the old one.

Is this wrong? Should the hospital have insisted the older, approved model be used, even if it knew that the newer device worked better?

In this case, the older implanted cardiac defibrillator delivered a painful 750 - volt shock to the heart when it detected an abnormal heart rate. In addition, the older version delivered unnecessary shocks 40 percent of the time. This compares to the newer device which delivers unnecessary shocks only five percent of the time, and due to improvements in its design, is able to deliver the shock at precise times, allowing for the use of a much smaller, less painful shock.

There are many people who would say that the use of a less effective device would be unethical, and policies or rules that insisted Medicare beneficiaries receive the older model would create a two-tiered system, in which government - funded patients received a lower standard of care.

I understand that there may be evidence that some physicians completed unnecessary - and sometimes dangerous - procedures or tests on patients receiving investigational devices. These tests or procedures were alleged to have been done to justify an admission or to allow the physician and/or hospital to bill for a legitimate procedure while their "real" procedure was one they knew would not be paid for.

Let me make one thing clear: those individuals or institutions that

knowingly put people's lives at risk for the sake of greed, or intentionally engaged in actions to defraud the government should be prosecuted to the fullest extent of the law.

Having said that, I must also state that I believe that most individuals engaged in medical research are honest. I do not believe that there is widespread fraud in the research community.

Let me state that again: It is hard for me to believe that over one hundred research hospitals - some of the premier medical institutions in the world - were bilking Medicare, knowingly or not.

HHS investigators seem to confirm this. HHS Investigators have been quoted in the *U.S. News & World Report* saying "Clearly, there were false [billing] claims, and we will pursue them." But, he added "we found that a majority of the cases were weak. No smoking guns." (*U.S. News and World Report*, December 18, 1995, p. 42)

HCFA had to know what was going on - that they were funding the use of highly sophisticated investigational devices - and paid for it, because it was the right thing to do. It was the right thing to do then, and is the right thing to do now.

We have, bar none, the best medical care available in the world today. That is due in no small part to the advances in medical science brought to the American people by the academic medical centers and research hospitals in this country. We excel in the field of medicine due to the innovation of the private and public sectors, and have developed a strong partnership to foster this activity. Let us make sure we balance the search for fraudulent behavior with reasonable care not to damage the majority of researchers who are engaged in honest, high quality research.

I fear that in our honest efforts to crack down on fraudulent behavior of a minority of individuals we will cause irreparable harm to the vast majority of honest researchers. We have seen how government can play a very important role in fostering innovation and research. We have also seen how heavy-handed behavior has shut down the same activity very quickly. I am told that many hospitals that previously supported research rapidly changed this policy and discontinued their support for research when HCFA began enforcing a rule many did not know existed in 1994. It was not until the new rule was published in 1995 that some of these institutions resumed supporting research.

We must not create a climate of siege upon our primer academic health centers. Weed out fraud and abuse - yes, stifle honest research and development - never.

I congratulate you, Senator Roth, for having these hearings today. We must do everything possible to prevent fraud and abuse within the Medicare system. However, we must balance the search for fraud and abuse with common sense, and not cause injury to innocent individuals as we look for criminals.

Thank you for the opportunity to provide the Committee with my viewpoint on this issue.

TED STEVENS, ALASKA, CHAIRMAN

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United States Senate

COMMITTEE ON
GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

March 15, 1996

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
Room 615F
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala:

As you know, on February 14, 1996, the Permanent Subcommittee on Investigations held a hearing that focused primarily on the improper and fraudulent billing of Medicare for procedures involving certain investigational medical devices, which has resulted in as much as hundreds of millions of dollars needlessly being paid by Medicare. Among the witnesses at this hearing was the Department of Health and Human Services (HHS) Deputy Inspector General, Jack Hartwig.

I am gravely concerned by the allegations of fraud and abuse we heard at this hearing. I was also disappointed by the failure of the HHS Office of Inspector General (OIG) to aggressively pursue these allegations.

In addition to the issues regarding possible Medicare billing fraud, I am particularly concerned about allegations involving possible patient abuse that were disclosed at this hearing, which I believe merit further investigation. Medicare patients must receive the best possible care and treatment. There is no room in the system for anything less. Therefore, I am writing to request that you instruct the HHS Inspector General to promptly and aggressively investigate these allegations.

In particular, I was shocked to learn of the existence in hospitals of a practice referred to as the "reimbursement balloon." Under this procedure, according to an anonymous medical industry witness, a physician will "re-invade the patient with a balloon solely for the purpose of creating an x-ray and paper trail to defraud Medicare." If true, this would constitute patient abuse, in addition to Medicare fraud, and should be dealt with most severely.

Senate Permanent Subcommittee
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Further, this same witness alleged that health care providers are re-using certain medical devices (e.g., ablation and electrophysiology catheters) and billing Medicare as if they were new medical devices. This practice also appears to constitute patient abuse since it carries with it the risk of needlessly exposing patients to carcinogens through these re-used devices and should also be thoroughly investigated as soon as possible.

I would request that you advise me regarding the specific action your Department takes to address these serious problems. Please have your staff contact Harold Damelin, Chief Counsel and Staff Director, at 202-224-3721 with any questions. Thank you for your assistance.

Sincerely,

William V. Roth, Jr.
Chairman
Permanent Subcommittee
on Investigations

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